



August 17, 2015

C. Edward Peartree
Director
Office of Defense Trade Controls Policy
U.S. Department of State
Washington, DC
By email to DDTCTPublicComments@state.gov

RE: ITAR Amendment – Amendment to the International Traffic in Arms Regulations:
Revision of U.S. Munitions List Categories XIV and XVIII (RIN 1400-AD03)

Dear Mr. Peartree:

I am writing on behalf of the Association of University Export Control Officers (AUECO), a group of 129 senior export practitioners with export control responsibilities from 100 accredited institutions of higher learning in the United States (U.S.). AUECO members monitor proposed changes in export control laws and regulations affecting academic activities and advocate for policies, procedures, and award terms and conditions that advance effective university compliance with applicable U.S. export controls and trade sanction regulations.

AUECO appreciates the opportunity to comment on the proposed amendment to the International Traffic in Arms Regulations (ITAR), Amendment to the International Traffic in Arms Regulations: Revision of U.S. Munitions List Categories XIV and XVIII, federal register notice June 17, 2015.

The adoption of this new proposed rule will have a negative impact on the academic research enterprise, especially those research institutions that regularly include foreign national students in their academic and research activities, and those which, by academic policy do not accept restrictions on publication of or participation in research. There are currently many research awards made to our member institutions from multiple federal and non-federal sources to conduct research involving one or more items in sections (b) through (h). The majority of these awards made to research institutions permit open dissemination of the research results, and there are no contractual restrictions on participation based on national origin. The biological agents listed in section (b) are governed by the EAR which allow for inclusion of foreign national students in most cases without a license. Moreover, these biological agents are also governed by the federal select agent program overseen by the USDA and CDC and the new Dual Use Research of Concern (DURC) regulations. Thus, multiple sets of regulations are already in place

to controls these agents while providing adequate flexibility for publication and foreign national inclusion.

General Comment on ITAR XIV(b)

We understand why the government wants to put stricter controls on technologies and activities that could potentially lead to the weaponization of biological agents. However, the proposed rule will likely cause confusion for compliance officers regarding which agency has licensing jurisdiction. This will increase the number of commodity jurisdiction requests submitted, increasing administrative workload for the submitting entity as well as the Departments of State and Commerce.

Request for Note to be Added to ITAR XIV(b)

NIH funds a large amount of research at universities for the identification, characterization, prevention and treatment of microorganisms and their associated diseases. This research should not be controlled under the ITAR. Because of the way the proposed regulations are written, NIH funded microbial research could fall under ITAR, which would seem counter to the charter of NIH. We recommend that a specific carve out be added to exempt NIH, CDC, and USDA funded work from ITAR controls.

Request for Wording Change on ITAR XIV(b)

ECCN 1C352 has been combined with 1C351 and removed from the Commerce Control List. Therefore, any mention of 1C352 should be removed from the proposed regulation.

Request to Reinstate Current ITAR XIV(n)

Section XIV(n) from the current USML has been removed in the proposed regulations. XIV(n)(2) contained an exemption for modifications to biological agents made for civilian applications (i.e., medical use). We do not understand the reason for the removal of this exemption, which is particularly useful to universities performing research.

Comments on ITAR XIV(b)(1)(i)

This section states that genetically modified biological agents where the modifications result in an increase in persistence in the field environment or the ability to defeat detection methods, personal protection, etc. would be controlled under the ITAR. However, a majority of the “properties” of microorganisms mentioned in XIV(b)(1)(i) are not something that researchers would typically test for, unless those properties were the subject of the research.

1. The lack of testing in these areas somewhat invalidates the usefulness of this paragraph. It does not seem appropriate to define the regulatory control environment around “properties” for which testing may not be completed (see example in 4 below).
2. There is a concern that the mention of these “properties” within the regulations may lead to requirements for mandatory testing of these “properties” for genetically

modified versions of the microorganisms listed in XIV(b)(1)(ii). Mandatory testing could create a significant burden on research laboratories from workload, cost, schedule and documentation standpoints.

3. What standards do we use to make a determination that a genetic modification has increased a microorganism's environmental persistence, decreased its ability to be detected or overcome natural host immunity? Will there be a uniform set of standards to help guide researchers in making this determination or will individual research labs need to develop these standards themselves? Allowing labs to set their own standards could result in differences in determining which regulation (ITAR or EAR) may apply. For example:
 - a. Lab Differences – Labs may have difference standards regarding the “properties”. Two labs conducting research on the same virus may have separately determined that the virus can survive temperatures up to 170°F (lab 1) and 155°F (lab 2). They each make modifications to the virus and they both measure that the “modified’ virus can survive temperatures up to 170°F. Therefore, lab 1 would state that the modification did not increase the virus’s environmental persistence, whereas lab 2 would conclude that the change did increase its persistence.
 - b. Interpretation of Change – A lab genetically modifies a controlled virus and finds through testing that the “genetically-modified” organism now appears to be able to survive temperatures up to 170°F, whereas the unmodified virus appears to survive in temperatures up to 160°F. Although this appears to be a “real” increase in persistence, some researchers may state it is not a statistically significant increase, or is of no practical importance (i.e., for transmission or sterilization purposes). Therefore, some labs may consider this genetically modified organism as ITAR-controlled and others may consider it EAR-controlled.
4. Such testing can delay license application reviews. For example, we submit a license application to BIS to ship genetically modified *Bacillus anthracis* to France. After initial screening, the reviewer asks us if the modification makes the bacteria more resistant to extreme hot or cold temperatures, or can defeat normal detection methods. We state “we don’t know; we never tested for that”. What happens to our application at that point? Is it put on indefinite hold until we conduct the tests and provide the results? Is it assumed to be subject to ITAR, even though that was not the subject of the research, nor is there evidence to indicate an increase in these “properties”? Is the application RWA’d for lack of information?
5. Based upon the “e.g.” in XIV(b)(1)(i)(A), the list of “properties” is incomplete. If this is the criteria for determining whether the subject microorganisms are ITAR or EAR

controlled, this list should be complete in the regulations and not subject to change through administrative guidances or reviewer preference.

6. To eliminate the potential confusion and issues caused by these “property-based” regulations, we would recommend the control be based upon the nature of the research to be conducted with the subject microorganism.
 - a. Research regarding the identification, characterization, prevention or treatment of the subject microorganism or its associated disease would be controlled under the EAR.
 - b. Research used to (1) increase the microorganism’s persistence in the environment, or (2) defeat detection methods, personal protection, host immunity, etc. would be controlled under the ITAR.

Although this may seem like a subtle difference from what is currently written, the difference lies in the intent of the research. Research that is intended to characterize a disease (of one of the subject microorganisms) will likely not test for many, if any, of the stated properties. However, research intended to defeat detection methods will likely test for that property.

Comments on ITAR XIV(b)(2)(ii)

As evidenced by the “e.g.” in XIV(b)(2)(ii)(A) and (B), the list of “properties” is incomplete. If this is the criteria for determining whether the subject microorganisms are ITAR or EAR controlled, this list should be complete in the regulations and not subject to change through administrative guidance or reviewer preference.

Comments on ITAR XIV(f)(1)(ii), XIV(f)(2) and XIV(f)(2)(ii)

The phrase “...developed under a Department of Defense contract or other funding authorization” is unclear. If this phrase is attempting to capture multiple funding vehicles under DOD, it should be changed to “...developed under Department of Defense funding.”

Research toward the development of new vaccines and therapeutics is currently funded by DOD as well as other sponsors. This research is intended to benefit and the vaccines/therapeutics be used to protect public and veterinary health against any event resulting from exposure to naturally occurring or non-naturally occurring pathogens. The proposed rule may inadvertently prevent this basic research and hinder the ability to develop or utilize these vaccines using the proposed language in the following ways:

Preparation of agents with non-naturally occurring genetic mutations are a necessary step in the process to understanding how an organism replicates, persists and to ultimately developing a vaccine. For example, investigators often introduce specific mutations or deletions within the organism to better understand how that organism replicates, survives and is transmitted to

another organism. These are critical steps in the development of new vaccines and therapeutics. Thus, understanding how the organism survives under extreme temperatures or arid conditions, how these conditions affect transmission, etc. will impact vaccine development.

The current broad interpretation of the language, specifically “persistence in the field”, will preclude this research from its traditional fundamental research status to a restricted status. Since these pathogens largely fall under the jurisdiction of the Select Agent or DURC policies already (e.g., *F. tularensis*, *Y. pestis*, certain strains of influenza, *Burkholderia spp.*), other regulatory processes are already in place to monitor these studies. Thus, it will be necessary to clarify the language and not duplicate efforts that will hinder basic science research.

AUECO appreciates the opportunity to provide the Department of State with the above comments on ITAR Amendment-Category XIV to enable the government to understand how the technologies we are developing and using are impacted by export controls. The research enterprise in the United States is critical to the economic advancement of our country and having export regulations that are not overly broad ensure that innovation is not stifled in performing fundamental research.

Sincerely,

A handwritten signature in blue ink that reads "JJ Souface". The signature is stylized with large, flowing loops for the letters "J" and "S".

Chair

Association of University Export Control Officers

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