AMERICAN SOCIETY FOR MICROBIOLOGY

Public and Scientific Affairs Board

August 17, 2015

Regulatory Policy Division
Bureau of Industry and Security
U.S. Department of Commerce, Room 2099B
14th Street and Pennsylvania Avenue NW
Washington, DC 20230

Re: RIN 0694–AF52

The American Society for Microbiology (ASM) commends the ongoing efforts by the US Department of State and US Department of Commerce to update and further clarify federal control regulations for Category XIV materials (Toxicological Agents, Including Chemical Agents, Biological Agents, and Associated Equipment) included on the United States Munitions List and the Commerce Control List. These regulations have a significant influence on the microbial sciences and on public health.

The departments' recent proposed rule changes for the Export Administration Regulations (EAR) and the International Traffic in Arms Regulations (ITAR) represent important steps in balancing national security against Category XIV threats with robust scientific research on such agents and relevant information exchange among researchers. The amended regulations, published in the Federal Register, include:

- Revisions to Definitions in the Export Administration Regulations [RIN 0694-AG32], Department of Commerce
- International Traffic in Arms: Revisions to Definitions of Defense Services, Technical Data, and Public Domain; Definition of Product of Fundamental Research; Electronic Transmission and Storage of Technical Data; and Related Definitions [RIN 1400-AD70], Department of State
- Commerce Control List: Addition of Items Determined to No Longer Warrant Control Under United States Munitions List Category XIV (Toxicological Agents) or Category XVIII (Directed Energy Weapons) [RIN 0694-AF52], Commerce
- Amendment to the International Traffic in Arms Regulations: Revision of U.S. Munitions List Categories XIV and XVIII [RIN 1400-AD03], State

The ASM is concerned that the proposed definition of fundamental research, as stated in RIN 1400-AD70, fails to adequately encompass the full scope of activities and outcomes of such research. We agree with other stakeholders who have questioned specifics of the new definition, such as the omission of software as part of technical data derived from fundamental research, or certain restrictions tied to proprietary information review by

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research sponsors. The too narrow definition has significant impacts on both the research community and the export of US technology.

The ASM supports the proposed rule revisions that would allow the transfer of certain Category XIV materials from ITAR's export control jurisdiction to the Commerce Department's EAR jurisdiction [RIN 0694-AF52; RIN 1400-AD03]. Other changes include needed clarifications on materials developed under Department of Defense funding. The stated intent of the revisions also includes clarification of which agents are controlled by the respective jurisdictions. Category XIV contains multiple microorganisms and toxins utilized in basic and applied research, important to both ensuring national security and improving public health. The ASM has consistently argued that any guidelines relevant to this research must be clearly understood and regularly reviewed for possible revision. The ASM believes that due to the rapidly changing scientific advances and epidemiology of many of the microorganisms listed in Category XIV, a review of the list now seems warranted.

We appreciate this opportunity to comment on the proposed changes.