AMERICAN
SOCIETY FOR
MICROBIOLOGY

Public and Scientific Affairs Board

October 23, 2003

The Honorable Tommy Thompson
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: 42 CFR Part 73
Possession, Use and Transfer of Biological Agents and Toxins Interim Final Rule

Dear Secretary Thompson:

The American Society for Microbiology (ASM) is writing to express its concern that critical scientific research may be seriously disrupted by the current applicability date of November 12, 2003 for full compliance with all provisions in the Interim Final Rule implementing Title II of the Public Health Security and Bioterrorism Preparedness and Response Act (Act), Public Law 107-188. We urgently request that, in accord with sections 202(c) and 213(d) of the Act, the Department of Health and Human Services and the Department of Agriculture take immediate action to extend the applicability date in the Interim Final Rules for a period sufficient to permit the federal government to complete the security risk assessments, background checks, and other tasks required of it by the Act and Interim Final Rules in a manner that minimizes the disruption of research or education projects involving select agents and listed biological agents and toxins.

The ASM is the largest single life science society in the United States with over 42,000 members dedicated to the study and advancement of scientific knowledge of microbiology for the public benefit. Many of ASM's members are engaged in research and other scientific work involving the possession, use, and transfer of select agents and listed biological agents and toxins. The ASM has been informed that, notwithstanding individual and institutional compliance with the extraordinarily tight deadlines for submission of names for the entity, the Responsible Officials, the Alternate Responsible Officials, and individuals needing access to select agents for clearance by the federal government, the federal government has not completed its screening obligations according to the time frame in the Interim Rules for Select Agents and Toxins. Indeed, it appears that screening has not been completed for the vast majority of such entities, Responsible Officials, Alternate Responsible Officials, and individuals, and it is highly unlikely that the federal government will complete these tasks prior to the current applicability date of November 12, 2003, for full implementation of entity registration in the Interim Final Rules.

In its comments on the Interim Final Rules, ASM warned that the transition timeline for implementation of certain requirements was extremely tight and expressed concern about whether entities and the government would be able to complete the process without delaying and discouraging research on biodefense and infectious disease. The ASM specifically commented that "the compliance deadlines

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should permit efficacious implementation of the statute and be consistent with the directive of Section 202(c) which states that the Interim Final Rule 'shall include time frames for the application of the Interim Final Rule that minimize disruption of research and education projects . . . .'" Obviously, institutions and individuals cannot continue scientific research and education in contravention of the Interim Final Rules. Therefore, if the federal government fails to complete its screening processes by the applicable date in the Interim Final Rules, rather than advancing the goals of the Act, the Interim Final Rules will cause the delay and/or abandonment of scientific research that is important for homeland security and for the general welfare of the American people.

Adverse results from failure to complete screening or to extend the applicability date would include:

- Interruption and potential loss of research projects critical for biodefense, public health and the battle against infectious diseases;
- Potential irrevocable loss of essential biological resources because cultures may be destroyed for security reasons or may die if they cannot be curated; potential loss of animals used in vaccine and therapeutic trial experiments and associated long term research results; and
- Potential redirection of research away from biodefense with associated loss of commitment of highly talented researchers.

Certainly, entities and individuals that have complied with their obligations under the Interim Final Rules should not suffer injury as a result of the inability of the federal government to promptly complete background screenings. Just as importantly, the national interest in scientific research and education should not suffer injury as a result of delays in screening. For these reasons, ASM requests that the federal government devote all available resources to the screening and that, consistently with sections 202(c) and 213(d) of the Act, the applicability date in the Interim Final Rules be extended until screening is completed for entities and individuals who filed under the Interim Final Rules.

This is a matter of substantial national interest. We earnestly request your immediate attention to addressing the security risk assessment process and applicability date for approved registration in the Interim Final Rules. As always, ASM stands ready to assist in the achievement of the important goals of the Act and the Interim Final Rules.

Sincerely,

Thomas Shenk, Ph.D. President, ASM	Gail H. Cassell, Ph.D. Chair, Public and Scientific Affairs Board	Ronald M. Atlas, Ph.D. Past President, ASM	Kenneth I. Berns, M.D., Ph.D. Chair, Task Force on Biological Weapons Control

cc: Attorney General John Ashcroft, Department of Justice
Dr. John Marburger, Director, Office of Science and Technology Policy