

February 10, 2003

Select Agents Program
Centers for Disease Control and Prevention
1600 Clifton Road, E-79
Atlanta, GA 30333

**RE: Interim Final Rule on Possession, Use and Transfer of Select Agents and Toxins
(Federal Register Notice, Dec. 13, 2002)**

The Federation of American Societies for Experimental Biology (FASEB) is pleased to have the opportunity to comment on the Interim Final Rule regarding select agents (42 CFR Part 73). FASEB is a coalition organization of 22 societies representing more than 60,000 biomedical research scientists. Many of our members are actively engaged in research related to select agents which has direct application to protecting our nation against disease, naturally occurring or as a result of bioterrorism. We support efforts to keep hazardous agents and toxins out of the hands of individuals who might use them for harm. As such, FASEB is eager to work with the federal government to ensure that regulations are put in place that allow this important research to continue, while at the same time strengthening the safety and security of our homeland.

FASEB concurs fully with the thoughtful comments generated by our colleagues at the Association of American Universities (AAU), American Council of Education (ACE) and Council on Governmental Relations (COGR) who represent the majority of the research institutes who will be most affected by these new regulations. We urge the Department of Health and Human Services (DHHS) and the United States Department of Agriculture (USDA) to carefully review and address the concerns expressed by AAU et al. In particular, we feel that the inconsistencies in the regulations promulgated by the Centers for Disease Control versus those produced by the Animal and Plant Health Inspection Service highlighted within the institution group's comments need to be resolved. These inconsistencies only serve to make a complicated, albeit necessary, process more confusing. Moreover, we strongly support the recommendation, voiced by the Howard Hughes Medical Institute and American Association of Medical Colleges, that a single office be created jointly by DHHS and USDA to handle all issues related to select agents.

FASEB would like to emphasize several points of particular interest to our membership:

Security Risk Assessment: The Interim Final Rule provides little specific detail as to what the security risk assessment entails. It is unclear what identifying information needs to be submitted to the Attorney General, nor by what process submission occurs. Given that the April 11, 2003 deadline is approaching rapidly, there could be a significant delay in life saving research if this process continues to lack definition. We urge DHHS and USDA to work with the Attorney General to produce a clear set of guidelines for this assessment as quickly as possible. Furthermore, we respectfully suggest that you solicit input from a broad spectrum of research entities in developing the requirements for the security risk assessment, as many of them may be restricted by institutional policies or state laws regarding what personal information about employees may be released.

Ambiguous terms: FASEB has concerns about the vague usage of the terms “area” and “access” in regards to controlling entry to labs where work with select agents takes place. As currently written, it is quite easy to interpret “area” as the entirety of the laboratory space. Requiring everyone who enters a large laboratory (i.e., has “access”) to obtain a security clearance and proper training, or have an escort constantly present, seems unreasonable. We would recommend that select agent policies mirror those that many universities use to contain radioactive materials, under which control is applied at the primary level of storage and use. For example, select agents could be stored securely locked in a box, freezer or cabinet, prohibiting access to restricted personnel, while still allowing for unrelated experiments to continue in the laboratory space. When the select agents are actually in use, all of those working in the vicinity or with select agents must certainly be properly cleared, trained and supervised. But is it truly necessary to impose such restrictions to all laboratory personnel who share common space but are not directly using select agents? We would underscore the concern raised by AAU, ACE and COGR that many researchers share expensive, specialized equipment, often kept in different lab rooms, and that duplicating such equipment in order to isolate an entire laboratory for select agent usage would be a significant logistical and financial burden.

Timeframes: While the regulation are quite clear in outlining a series of deadlines by which individuals and entities must comply with the Public Law 107-188, timelines mandating completion of the registration and security reviews by DHHS, USDA and the Attorney General are nonexistent. Because there is still no clear indication of what the security review involves, we fear that researchers and institutions could fully meet the deadlines for submitting the required information only to encounter long delays in review of the application. What is a researcher or entity to do in such a scenario: bring research that could have enormous health benefits to a halt while waiting for proper certification? Or risk criminal penalties for not meeting the strict requirements of the select agents regulations? Surely this was not what Congress intended in drafting this legislation. Thus, FASEB recommends that DHHS and USDA develop a transitional process that allows ongoing research to continue, provided the entity’s risk assessment and registration applications are complete.

The biomedical research community acknowledges the necessity of creating new regulations to minimize the risks from bioterrorism. We are eager to assist in reassuring the public that they are safe from those who would abuse select agents, while maintaining public trust in the benefits of science. FASEB hopes that the federal government will continue its active dialogue with the scientific community in developing measures to protect the public and allow critical research progress to be made. Please do not hesitate to contact us if you have additional questions or concerns.

Sincerely,

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President, FASEB