January 26, 2010

Jessica Tucker, Ph.D.
Office of Medicine, Science and Public Health
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
330 C. Street, SW
Washington, DC 20201

Re: Comments Submitted in response to Docket ID # fr27no09-73
Federal Register Notice: November 27, 2009 (Volume 74, Number 227)
Screening Framework for Synthetic Double-Stranded DNA Providers

Dear Dr. Tucker:

The American Phytopathological Society (APS) submits the following comments in response to the notice entitled: Screening Framework Guidance for Synthetic Double-Stranded DNA Providers, which was published in the Federal Register on November 27, 2009, by the Office of the Secretary, Department of Health and Human Services.

The APS is the premier society dedicated to high-quality, innovative plant pathology research with over 4,500 members from academia, government, industry, and private practice. The APS acknowledges the risks associated with *de novo* DNA synthesis and appreciates the government's efforts to stem potential misuse of synthetic biology. We emphasize that any approach to minimizing risks should facilitate scientific advancement by preserving legitimate researchers' access to synthetic DNA and avoiding undue burdens on synthetic DNA providers. The APS generally supports the Guidance, but we suggest further consideration of the following concerns.

PROVIDE A CENTRALIZED DATABASE OF PROSCRIBED ENTITIES. The Guidance recommends that providers "screen customers against several lists of proscribed entities". A centralized database of U.S. Government proscribed entities would streamline this process. In addition, a list of "denied customers" could be shared between providers. The proposed framework is daunting, cumbersome, and could be extremely time-consuming, all of which would impact profitability of U.S. enterprises and delay research that the government allegedly encourages.

FORMULATE A DATABASE OF HARMFUL SEQUENCES. The HHS Select Agents and Toxins List was identified in the Guidance as the most appropriate list for screening sequences against agents of concern. The Guidance also suggests that foreign orders be screened against the EAR Commerce Control List. A database in which these two lists are combined

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could be augmented over time as the scientific community identifies harmful sequences. This database would be a useful tool for providers.

PROVIDE A SINGLE GOVERNMENT CONTACT FOR PROVIDERS
The Guidance recommends that providers contact one of a number of agencies "in cases where follow-up screening cannot resolve an issue raised by either customer screening or sequence screening". We strongly suggest that the government identify a single source that a provider may contact in such cases. A combined list could encourage appropriate communication among the mentioned agencies.

DEVELOP TOOLS FOR MEASURING THE SUCCESS OF THE GUIDANCE.
The U.S. Government should remain flexible and maintain an open dialogue with providers and the scientific community. Metrics should be developed to measure the success of the Guidance. The following questions should be addressed: How many providers are complying with the screening recommendations? As the demand for synthetic DNA grows, do the costs associated with screening become prohibitive? Are legitimate researchers being denied access to synthetic DNA services?

The Department of Health and Human Services has provided a thoughtful document that recognizes both the risks associated with and the many benefits of synthetic biology. We appreciate the opportunity to comment on the screening framework and hope that these comments are of assistance.

Sincerely,

Jacqueline Fletcher, Ph.D.
Chair, APS Public Policy Board