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CDC AND APHIS PUBLISH FINAL RULES ON REGULATION OF SELECT AGENTS

The March 18, 2005 Federal Register contains publication of final rules on the Possession, Use, and Transfer of Select Agents and Toxins, by both the Department of Health and Human Services and the U.S. Department of Agriculture. The final rules are effective April 18, 2005. Both agencies provide commentary on the changes made in the final rule compared to the interim final rule which was published in February 2003. The agencies also describe the comments received on the interim final rule, and whether or not such comments led to revisions in the final rule. The USDA-Animal and Plant Health Inspection Service (APHIS) has posted a set of FAQs at www.aphis.usda.gov/programs/ag_selectagent/FinalRuleQ&A.pdf

The DHHS-Centers for Disease Control and Prevention (CDC) has not yet posted such a document.

Below is a summary of some of the changes in the final rule, particularly with respect to the comments submitted by COGR, AAU and ACE on the interim final rules. **However, it is strongly recommended that you bring the final rules to the attention of your institution's Responsible Official(s), Biosafety Officer, Legal Counsel, Vice President for Research, Principal Investigators, and anyone else involved in the process for ensuring proper handling and safeguarding of select agents.**

Resolution of Comments submitted by COGR et al:

1. 42 CFR Part 73.4 and 73.5 Select Agents and Toxins -There were several inconsistencies in the interim final rules between APHIS and CDC, beginning with the terminology used for select agents. In the final rule, APHIS has dropped the terms "biological agents and/or toxins", "listed agents and/or toxins", and "high consequence livestock pathogens", and adopted the CDC term "select agents or toxins". Also, we pointed out that both the definition and regulation of genetic elements and genetically modified select agents was inconsistent in the interim final regulations, and recommended that APHIS adopt the CDC definition and treatment of genetic elements. APHIS agreed and has adopted the CDC approach for genetic elements.

2. Part 73.8- Security Risk Assessment - Under the interim rules, security risk assessments done by the Attorney General were required for an individual who owns or controls the entity. COGR pointed out that there is no such individual at a university, and recommended that the risk assessment be required only for the Responsible Official and individuals having access to select agents. CDC and APHIS revised the final rule to state that public institutions of higher education are exempt from the requirement to have a security risk assessment for the

individual who owns or controls the entity. For private institutions of higher education, an individual is deemed to own or control the entity if they are in a managerial or executive capacity with regard to the entity's select agents, or with regard to the individuals with access to the select agents. This point was addressed earlier via an FAQ on the CDC Select Agent Program web site at www.cdc.gov/od/sap/. Since that time our private university members have adopted various approaches to determine who such individuals are- some follow a chain of command process, going up the chain from the Responsible Official, or from the PI(s) working with select agents. Others selected one or two key university officials as the individual with managerial or executive capacity.

3. Part 73.11 - Security - We recommended that the terms area and access be re-defined to narrow the scope of applicability of the select agent rules, and to reduce the possibility for differing interpretations by institution and federal officials. CDC and APHS agreed, and have eliminated references to area and use it in the regulations only when it is clear in context. Access has been re-defined to clarify that "An individual will be deemed to have access at any point in time if the individual has possession of a select agent or toxin (e.g. ability to carry, use, or manipulate) or the ability to gain possession of a select agent or toxin".

With respect to security plans, CDC and APHS language in the security section of the regulations is now identical, to ensure consistency. With respect to compliance inspections, COGR commented that agency inspection teams should include professionals with scientific expertise, not just financial auditors. No changes were made to the regulations, but CDC and APHS state that they agree with the comment, and state that "our inspection teams include individuals who meet the criteria suggested by the commenter". Also, CDC and APHS state that compliance inspections for security will be based on the regulations and inspectors will be looking for security that provides graded protection commensurate with the risk of the select agent or toxin, given its intended use.

The CDC and APHS state that they are working with interagency groups and security experts to draft a document that will provide additional guidance about the security required for select agents and toxins, and that this document will be available in spring 2005.

Finally, COGR had commented that the interim regulations were unclear with respect to package inspections, in both the scope of the inspection and who should conduct the inspection. CDC and APHS revised the final regulation to state that entities are required to inspect only suspicious packages. No change was made to specify who should conduct the inspection, as the agencies believe that the entity would be best able to determine the most appropriate and qualified individual for this activity.

4. Part 73.12 Biosafety - With respect to the entity's security plan, the regulations now require that "The plan must be reviewed annually and revised as necessary. *Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan.* The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident." (emphasis added)

5. Economic Impact- Both CDC and APHIS revised their cost impact analysis of the regulations, based partly on data submitted by commenters and partly on their own data. The revised figures reduce the estimated cost impact since, according to CDC and APHIS, fewer entities and individuals ended up seeking registrations and risk assessments. APHIS provides a particularly detailed analysis of the costs of implementing various parts of the regulations. In the final analysis, the agencies state that the benefits, in terms of preventing catastrophic events, far outweigh the costs. As to the COGR argument that federal funding should be provided to offset at least some of the costs, the agencies state that the legislation provided no authority or funding to pay for the costs.

As stated above, these final rules should be closely reviewed. There are revisions by both CDC and APHIS to the list of select agents and toxins that fall under the regulations, and other changes that may be of particular interest to your institution on training and the duties of the Responsible Official.

Revised FBI Form - A new version of the FD-961 form is now available. This is the form required in order for the FBI to conduct risk assessments for individuals needing access to select agents. This form replaces the older version and should be used when submitting new forms to the FBI. According to APHIS, the form has easier to read instructions and has an extra page added for foreign born individuals to complete. The website address to access the form is available at www.fbi.gov/terrorinfo/bioterrorfd961.htm