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COUNCIL ON GOVERNMENTAL RELATIONS

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December 2, 2011

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Charles L Divan, Branch Chief
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SUBJECT: Possession, Use and Transfer for Select Agents and Toxins:
Biennial Review (CDC-2011-0012)

Agricultural Bioterrorism Protection Act of 2002: Biennial
Review and Republication of the Select Agent and Toxin List;
Amendments to the Select Agent and Toxin Regulations
(APHIS-2009-0070)

Dear Drs. Weyant and Divan:

The Council on Governmental Relations (COGR) is an association of 188 research universities and their affiliated academic medical centers and research institutes. COGR concerns itself with the influence of federal regulations, policies, and practices on the performance of research conducted at its member institutions. COGR members perform a significant share of the Federally sponsored extramural research involving select agents and toxins (SAT) in partnership with Federal agencies. As a key research performer, we are deeply interested in proposed changes to the regulations governing that activity.

Since the strengthening and expansion of the regulations governing the possession, use and transfer of select agents and toxins in response to Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (PL 107-188), the research community has appreciated the efforts of the Centers for Disease Control and Prevention (CDC) and Animal and Plant Health Inspection Service (APHIS) to create a common regulatory approach to assist the research community in ensuring the safe and secure use of select agents and toxins in critical research.

Since the President signed Executive Order (EO) 13546, Optimizing the Security of Biological Select Agents and Toxins in the United States (July 2010), we have anticipated the report and recommendations of the Federal Experts Panel with regard to addressing the creation of tiers of SAT beginning with the designation of Tier 1 SAT that present the greatest risk of deliberate misuse. The Panel was directed to examine options for graded protections of Tier 1 SAT and consider the overall reduction of the number of agents and toxins on the Select Agent List.

We welcome the work of the CDC and APHIS in addressing the Federal Experts Panel's recommendations as reported in November 2010. COGR will defer to the community of scientists to comment on the SAT selected for inclusion in the list of Tier 1 agents and appreciate the reduction of the list of SAT as well. But we must express our disappointment with the overall outcome. We are not confident that the proposed regulations meet the crucial balance between increasing the nation's security and reducing the hurdles faced by scientists as they pursue research on potentially dangerous SATs.

In responding to the proposed amendments to the regulations, we will use references to the CDC Possession, Use and Transfer of Select Agents and Toxins (42 CFR Part 73) because these regulations have a broad reach and for the convenience of citations, etc. As applicable, our comments can be inferred for the US DA Select Agent and Toxins regulations as well [7 CFR Part 331 and 9 CFR Part 121].

Creation of Tiers

We anticipated that efforts to tier the SAT list would include an assessment of all SATs to identify those to be placed on a Tier 1 list, those to be removed from the list and, for those that remain an assessment or ranking of the agents and toxin based on risk. We looked forward to tiered requirements based on this evaluation of risk for all of the SAT including Tier 1 in hopes that the requirements would reflect the level of risk for misuse, theft, loss and accidental release.

What is proposed is heightened security for identified Tier 1 SAT and increased security requirements for those SAT remaining on the principal or non-tiered list. The security requirements have increased the regulatory burden and costs across all SAT. Thus, the proposed regulatory changes fail to achieve the goal of minimizing the impact of the regulations on the legitimate uses of SAT in research; research that the EO notes is essential to national security.

New Non-Tier 1 Requirements

Transfers

The new sections dealing with transfer of SAT [73.3(d)(3)(ii) and 73.16 (l)] require that a registered individual or entity exercise and document the individual's or entity's due diligence in affirming that a recipient has legitimate need for a toxin of a type or in an amount that is excluded under the provisions of 73.3(d)(i). The direct and immediate effect of this requirement is to negate the positive scientific effect of the exclusions at 73.3(d)(i). The exercise of due diligence and the documentation of that due diligence establish a new access requirement and a new record keeping requirement for materials previously excluded from the requirements. If the exclusions from the requirements are appropriate for both scientific and security purposes – and we agree with the CDC and APHIS that these exclusions are appropriate – such a requirement will result in a significant

increase in burden and cost as well as profound deterrents to the conduct of research with, we suspect, little if any effect on security.

At a minimum, entities will need to extend tracking and inventory procedures to these SAT in order to complement the documentation of due diligence. This requirement will, at the very least, discourage the exchange of materials among scientists, thus, frustrating scientific progress. It is unclear if the transfer exemption included in the footnote at 73.16(a)4 – exempting transfers within an entity covered by the same registration – applies to the requirement at 73.3(d)(ii). If it does not, the burden of tracking, inventorying and documenting due diligence will increase exponentially. Finally, it is unclear if the exclusion from the requirements offered in 73.3(d) continues to apply with such transfer in that prior authorization is not required.

The proposed rule offers no direction on the meaning of “due diligence” in discerning need in this context. “Due diligence” is not a useful measure; and any alleged failure to exercise appropriate due diligence places the individual or entity in jeopardy of penalties under 73.21. If CDC and APHIS persist in including these new requirements, a realistic measure would be a determination “to the best of the individual/entity’s knowledge.” In a similar manner, reporting any “known or suspected violation of Federal law or suspicious activity” [73.3(d)(3)(iii) and 73.16(l)(2)] puts the transferor at risk. If these requirements remain, the standard should be actual knowledge or evidence of a violation of Federal law.

Information Security

The new requirements at 73.11(c)(9) for information security increase the administrative burden and costs because they apply across all SATs at the institution. The creation of new requirements such as the information security plan heightens our concern with the failure to tier all SAT by the associated risk. It is unclear what information is to be secured under the required plan given the wide swath of “SAT-related information, files, equipment and applications” included in the provisions. Entities can “provide for” some measure of information security but can rarely “ensure” that all elements outlined in information security plan will be met consistently without interruption across the entity. Being held to this standard will create virtually automatic violations.

If there is greater clarity in the types of “information” involved and a rationale for the level of security required, entities should be permitted to address the CDC’s and APHIS concerns using an approach scaled to the threat of risk associated with varying SATs and the related information. For example, references to “external connections” we assume to mean connections to the registered space and not the entire institution; and the information to be secured is related to the SAT use in the facility or the registered space itself as opposed to documents created to conduct analysis or report results. Further, agent-specific information, commonly available on the Internet, is placed in standard operating procedures documents on public websites. These documents are SAT-related information and, yet, they are of no consequence with regard to security and should not be swept into this requirement. Absent greater flexibility, entities may be forced to isolate all such SAT-related “information” – an expensive and not necessarily foolproof approach. Using a more flexible approach, a more reasonable standard might be to provide for systems that monitor for attempted modifications and/or disruptions including unauthorized access but only facilities-control information for registered spaces. Throughout the proposed requirements, we would include modifiers like “reasonable” or “reasonably commercially available” to minimize the administrative and financial impact of “ensuring” continuous controls while still providing for the integrity, confidentiality and availability of the information.

Access

Personnel Reliability

There has been a lively and on-going discussion of the most reasonable and viable mechanisms to provide for personnel reliability. The National Science Advisory Board for Biosecurity (NSABB) conducted a series of meetings including a public consultation to solicit ideas, effective practices, etc., to assist the research community in providing for the safe and secure use of SATs. We assume that the recommendations included in the NSABB report, *Guidance for Enhancing Personnel Reliability and Strengthening the Culture of Responsibility* (September 2011) were considered in drafting the proposed regulations and will be considered in drafting future, much-needed guidance documents. It is important to note that the NSABB was cautious in recommending extensive but unproven practices. Observing that some practices are redundant to the Security Risk Assessment process, others have privacy implications or are resource-intensive and of unproven or unsubstantiated value, the NSABB advocates careful consideration including a consideration of costs and benefits of each, any evidence for their effectiveness, and the likelihood of any unintended or detrimental consequences for the scientific enterprise.

With these recommendations in mind, we assume that measures like those recommended by the NSABB would meet the personnel reliability requirements for Tier 1 SAT security including pre-access suitability [73.11(e)(1)] and on-going assessment of suitability including self and peer-reporting, training, and on-going suitability monitoring [73.11(e)(3)].

“Restricted Person”

We are deeply troubled by the meanings used to define a “restricted person.” The use of an indictment or conviction by any jurisdiction, domestic and foreign, of a person for a crime punishable by imprisonment for a term exceeding 1 year is excessive. Some measure of discretion must be a part of any assessment of an individual. Some non-violent, non-terror-related crimes such as driving under the influence of alcohol in some jurisdictions carry a possible sentence of more than one year of imprisonment. Some indictments and convictions occur early in one’s life and a reasonable person would believe that behavior that has not been repeated in many years should not have a bearing on their ability to work with SAT. Some jurisdictions, notably foreign jurisdictions, have statutes that would result in indictments and convictions that simply would not be sustained in the US.

One can move through the list of elements that lead to the designation of a restricted person and question the reasonableness of the measures used in the assessment. Some jurisdictions allow the use of medical marijuana; some jurisdictions commit individuals to mental institutions based on behavior the jurisdiction considers immoral or demonstrates of a “mental defect” that the US would consider an exercise in free speech; finally, some members of the Armed Services of the US received dishonorable discharges for their sexual orientation. These are just some examples of the overly broad use of criteria for the determination of a “restricted person.” There must be a way to assess these criteria on an individual basis.

Responsible Official

We are puzzled by the proposed requirement that the responsible official must “have their principal duty station at the physical location of the entity” [73.9(a)(6)]. We are not persuaded that

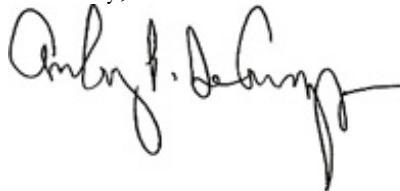
ensuring compliance and a quick response to incidents are sufficient rationale for this requirement. On the contrary, we could argue that compliance can be better maintained across an institution if there is a single responsible official rather than multiple officials that would result by exercising the option of the designation of alternates simply to meet the collocation requirement. Generally, individuals with the authority and responsibility to act on behalf of the institution hold a high-level or senior position or rank and collocation can conflict with ensuring the level of authority and responsibility consistent with the seriousness of these regulations.

Tier 1 Agents and Toxins – Costs and Burden

We recognize that those SATs that have been designated Tier 1 have been determined to pose the greatest threat to health and safety and, as such, require significant controls in the possession, use and transfer. It is important to observe, however, that the proposed security measures will diminish the ability of scientists to work with SATs. Some will become discouraged and self-direct their scientific inquiries into other areas of research; others will be at institutions that simply cannot afford to implement the requirements and, thus, be forced to change their research direction. Elements such as three different barriers are unclear – three different types or three different levels? – other elements will require, in some cases, significant modifications to systems for 24/7 monitoring and multiple back-up systems for man-made and natural events or disasters. We don't dispute the value of these measures however we are confident they will come with a cost to the scientific enterprise in the US. The unwillingness or inability of some scientists to continue to work to protect the US from biological threats or help protect the public health from naturally occurring epidemics must be weighed in the balance.

Thank you for the opportunity to comment.

Sincerely,

A handwritten signature in black ink, appearing to read "Anthony P. DeCrappeo". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Anthony P. DeCrappeo
President