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In Brief

Survey Finds Biodefense Researcher Anxiety—Over Inadvertently Violating Regulations

A nationwide survey of biodefense researchers assessed the effectiveness of the select agent regulations (42 CFR §73), which govern the handling, storage, and security of listed biological agents and toxins, in achieving their statutory goals of protecting public health and national security. The survey assessed regulatory components and measured an "anxiety factor," which indicated that respondents had high anxiety about inadvertently violating these regulations, leading to negative impacts on their careers and potentially thwarting the goals of the statute.

This nationwide study was conducted to assess whether the select agent regulatory program is meeting the statutory goals—protecting public health and national security. While Congress creates law, agencies have flexibility in how they design a program to implement laws. The Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (APHIS, part of the U.S. Department of Agriculture) are the agencies that design the regulations for laboratory biosafety and biosecurity, handling, storage, and transportation of the agencies' lists of "select agents" and toxins (42 CFR §73).

The email survey was administered in 2007 and 2008 using Inquisite®, with IRB approval. The test population was 509 principal investigators (PIs) and co-PIs throughout the United States who were funded to do biodefense research; there were 198 responses (39%).

Results

The survey tested the suggestion that biodefense researchers simply do not want select agents regulated, and it was disproved by a wide margin: 93.4% responded that select agents *should* be regulated.

Biodefense researchers surveyed indicated that the Biosafety in Microbiological and Biomedical Laboratories (BMBL) guidance was not as widely accepted as has been suggested, with 41% of respondents preferring clear regulatory guidance over the BMBL.[1] Instead of less regulation, respondents indicated that more specificity is needed for training requirements in BSL (88.4%), regulatory compliance (76.3%), and emergency response (61.1%) training, rather than merely what is "appropriate."[2]

One of the most controversial components, the inventory requirement, scored low, with 24.5% responding that the inventory approach is not useful at all.[3] A biosecurity background investigation of biodefense researchers[4] received higher marks, with 16.7% ranking this as the *most* effective component (among 10) of the regulation.

Given the concern about uncertainty in the regulation, and several high-profile civil and criminal matters, several "anxiety factor" questions were asked: "How concerned are you about inadvertently violating the select agent regulations, which would have negative repercussions on your career?," with 1 being the least concerned and 5 being the most concerned. The findings indicate a relatively high level of concern: 64% selected values of 3-5, on the high end of the continuum. For perspective, a comparative concern question was asked, with the same scale: "How concerned are you about injury or death in your work?" Many of the researchers surveyed work with the deadliest pathogens on earth, but a different response emerged: 84% selected values of 1-3, the low end of the continuum. While not a perfect mirror image (Figure 1), the suggestion of an inversely proportional relationship between these concerns presents a troubling public policy picture: the doubtful desirability of a regulatory program that provokes this very high level of anxiety among biodefense researchers over fear of inadvertently violating the regulations.

When respondents were asked whether they would use a hotline for legal compliance questions, guaranteeing anonymity, 59% responded affirmatively, further supporting

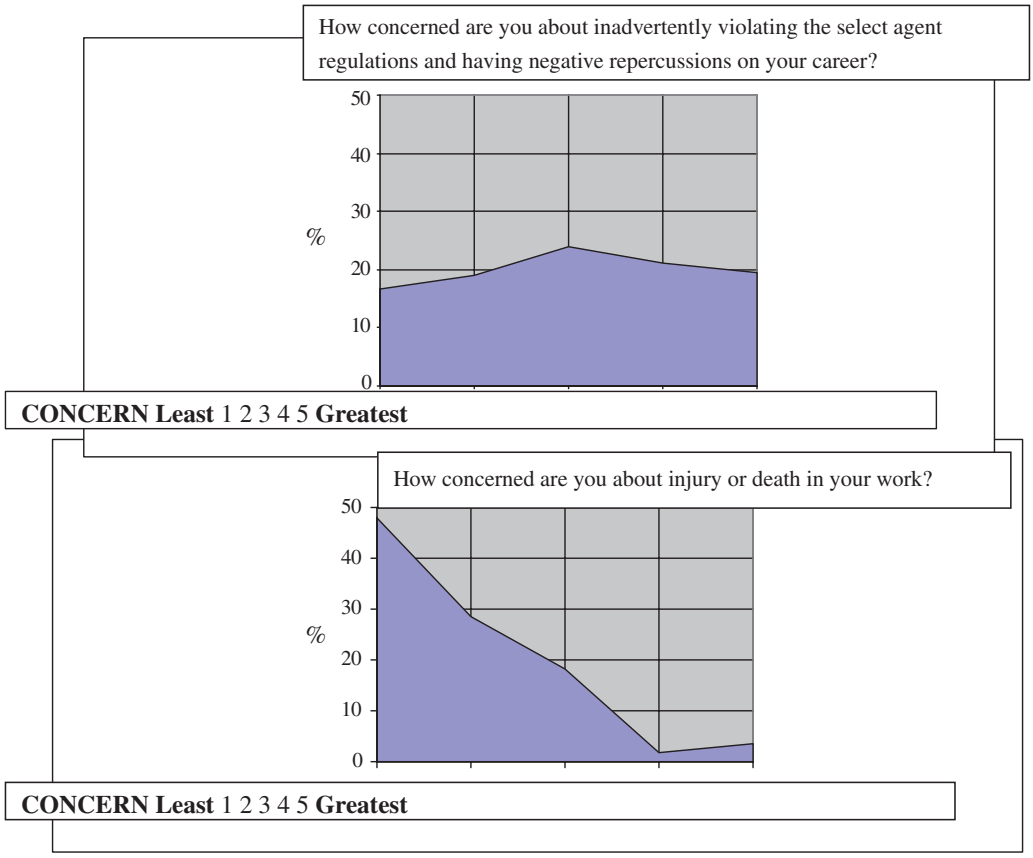

Figure 1. Sources of Concern for Bioresearchers.

the finding of significant concern for inadvertently violating the regulations.[5]

Conclusion

These findings indicate that the Select Agent Program, after its first 5 years, has flaws that may thwart it from achieving its statutory goals. Among the flaws is a measure of "anxiety" among those in the regulated community that suggests that the program should be reviewed, with an eye toward making it more effective and less anxiety provoking.

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References

1. 42 CFR §73.12 (1)(c).
2. 42 CFR § 73.15, Training. An entity . . . must provide information and training on biosafety and security to each individual . . . "; 42 CFR § 73.10(c): "Each individual with access to select agents or toxins must have the appropriate . . . education, training and/or experience. . . . "
3. 42 CFR §73.17 (a): "An individual or entity . . . must maintain complete records. . . . Such records must include (1) Accurate, current inventory for each select agent . . . held in long term storage. Including the name and characteristics . . . quantity . . . date of acquisition . . . when moved. . . . when used and purpose of use. . . . "
4. 42 CFR § 73.10 (A): An individual may not have access before being "approved by the HHS Secretary or Administrator, following a security risk assessment."
5. As a result of this response, the National Biosafety and Biosecurity Law Hotline, Center for Biodefense, Law and Public Policy, Texas Tech University (1-866-688-1320), was established in 2008.

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