



ABSA

American Biological Safety Association

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Gerald Epstein, Ph.D.
Co-Chair, Fast Track Action Committee
Deputy Assistant Secretary for Chemical, Biological, Radiological, and Nuclear Policy
U.S. Department of Homeland Security

RE: Office of Science and Technology Policy request for comments regarding impact of the Select Agent Regulations

Dear Dr. Epstein:

We appreciate your invitation to comment on the impact of the Select Agent Regulations (SAR) on the biosafety profession and public and private sector organizations we support (these include research and development, production, clinical and security/defense operations handling US Select Agents or Toxins (SAT). Many of these organizations are working at the cutting edge of science expanding the boundaries of human knowledge for the benefit of our nation. These are the organizations our country relies on to conduct the critical biological research, diagnostic testing, and production necessary to maintain human and agricultural health, national security and emergency response capabilities. Through these organizations our nation has successfully reduced the burden of disease both in this country and around the world, through the discovery and production of innovative therapies, vaccines, and cures.

While considering regulatory reform, The Office of Science and Technology Policy (OSTP) must ensure any changes made to the SAR support rather than undermine the health and well-being of our nation. We cannot fix our biological research enterprise by closing down facilities, removing their funding, or placing such a regulatory burden on organizations that they simply avoid work with SAT; these projects bring unique oversight and compliance challenges that often become all-consuming and counterproductive. While in some circumstances these regulations may help protect our country from intentional or unintentional release of these agents, the burdens these regulations have created on stakeholders are currently unsustainable, often impede activities and highlight the scarcity of high quality support to maintain the necessary local compliance programs. OSTP must evaluate existing requirements, identify areas to implement change, and verify changes identified will not impose costly or restrictive requirements that lack a public or economic benefit.

To address these concerns, ABSA offers three key recommendations for OSTPs consideration to improve the SAR at a national level:

- **Recommendation 1: Harmonize inspection results over time**
- **Recommendation 2: Advocate for and invest in workforce education, training, and credentialing**
- **Recommendation 3: Engage in a deeper dialogue**

We believe that by following these recommendations, the SAR will become more effective and will strengthen rather than impede critical biological research and production activities, as well as national security and emergency response capabilities. Below are further details regarding each of our recommendations.

Recommendation 1: Harmonize inspection results over time

One longstanding stakeholder concern with SAR compliance is the negative impact of inconsistent inspections. Since the promulgation of SAR, stakeholders have expended significant time, effort, and financial investment in order to reconcile inconsistent inspection results and overcome APHIS and CDC's reticence to formally respond to site-specific stakeholder compliance questions. ABSA advocates two easy-to-implement solutions to overcome inconsistent inspections and opaque regulatory guidance:

- 1) Adopt a *Letter of Interpretation* process - whereby entities can obtain definitive compliance responses from CDC (similar to OSHA) that are available to everyone, and
- 2) Adopt a *Uniform Inspection Report* template – a report template to compliment the inspection checklist, whereby it is completed sequentially and consistently between inspectors and is organized according to SAR section number (e.g. 42 C.F.R. § 73.1 through § 73.19)

These solutions will harmonize yearly inspection results, will enable inspectors and ROs to quickly and easily identify recurring deficiencies, and will give all parties a realistic view of inspection outcomes. ABSA encourages APHIS and CDC to seek stakeholder participation in implementing these solutions.

Recommendation 2: Advocate for and Invest in Workforce Education, Training, and Credentialing

An important asset to compliance with the SAR is an appropriately trained, knowledgeable workforce. An external advisory panel to the CDC (Recommendations of the Advisory Committee to the Director Concerning Laboratory Safety at CDC, published January 13, 2015) recommended that the safety department at the CDC be staffed with scientists having professional qualifications in research and/or laboratory safety as well as an understanding of requirements for compliance. In addition, the panel advised CDC to establish a standardized lab safety training curriculum across CDC, including the establishment of standardized methods for competency skills mapping and refresher training.

Currently, there is a lack of formalized training programs for biological safety practitioners; to our knowledge, no comprehensive degree programs exist to train biosafety professionals. There are only two fellowship programs, the National Biosafety and Biocontainment Training Program (NBBTP) and the Midwest Regional Center for Excellence (MRCE) Biosafety Fellowship Program. These programs train approximately 3-5 people per year, in total, to manage biological safety programs.

In addition to the lack of training programs for biological safety professionals, most institutions do not train future researchers adequately in the areas of biosafety and biosecurity. Researchers are trained to do research; the practice of safe and secure science is not part of this foundation in the university setting. Responsible research and ethics classes are required for graduate students, yet most institutions do not provide any formalized means to instill the importance of safety and security into this key demographic. This fundamental understanding and respect is critical to reducing complacency and influencing the way science is conducted. Complacency is a trait that many biosafety professionals face, is detrimental to a true culture of safety and is also a key factor in many accidents and potential exposures. Educating future researchers is the most logical place to start laying the foundation for generations of researchers who are equipped to embrace safety and security as well as work collaboratively with the biosafety professionals at their institutions.

Finally, many institutions add biosafety responsibilities to the already overburdened research staff conducting the Select Agent work, often as a cost-saving measure. This situation creates clear conflicts of interest between science and safety; it can also lead to increased institutional costs due to a lack of understanding of how to best invest their resources to comply with SAR regulations and respond to inspection findings. This must be rectified.

To address these training and competency needs, ABSA advocates implementing the following solutions:

- 1) **Require biosafety program leads to be competent in the field of biosafety and biosecurity.** Encourage and provide incentives for companies to hire credentialed biosafety professionals to administer compliance programs. ABSA offers the RBP (Registered Biosafety Professional) and CBSP (Certified Biosafety Professional) credentials as methods to validate professional competency.
- 2) **Require biosafety and biosecurity training as an integral part of an organization's biorisk management program.** Support the establishment of formalized degree programs and continuing education programs to train the next generation of biosafety professionals. Funding should also be dedicated to assessing and establishing key performance indicators, which could assist in compliance with the SAR. ABSA and other organizations offer biosafety officer training and continuing education courses to supplement Biosafety and Biosecurity Officer on the job training. In addition, ABSA believes formalized degree programs must be developed to train the next generation of biosafety professionals.

- 3) **Leverage biorisk mentoring programs to develop biosafety professionals.** In the absence of formal programs, training of biosafety professionals is usually achieved through a combination of courses offered by ABSA and others as well as mentoring by senior biosafety professionals. The mentorship model often leads to a variety of program types and methods to ensure safe working practices among various institutions. This flexibility has many benefits, including allowing programs to adapt to the unique culture of institutions and, in turn, achieving valuable buy-in from the researchers with regards to safety programs.
- 4) **Partner with ABSA members to acquire metrics and evidence-based best practices** to promote wider implementation of risk-based, cost-effective methods that promote both safety and compliance. Having access to better data could simultaneously improve compliance among institutions and reduce the need for inspector interpretations, thereby reducing the burden on all involved.

Establishing competency expectations for biosafety professionals, providing training and mentoring opportunities to biosafety professionals as well as personnel working directly with SAT, and partnering with ASBA and others to share good practices and lessons learned will strengthen SAT programs and compliance.

Recommendation 3: Engage in a Deeper Dialogue

The OSTP request for comments allows approximately 2 weeks for gathering feedback from our membership and writing a response. This is a good start to creating a constructive dialogue; however, much more time is needed to conduct surveys and gather empirical data on the true impact the SAR have had on institutions and individuals. There are countless anecdotal stories to share about researchers who leave or avoid SAT research or the sheer volume of paperwork one Responsible Official must maintain for a select agent that is already established in the environment. These stories and the lessons learned need to be shared.

ABSA recommends that it is in the best interests of CDC, APHIS, the research community and biosafety professionals if we engage all stakeholders and move forward together to make the SAR more transparent and less burdensome; we need to find a way to invest in education for future scientists and biosafety professionals. We recognize the importance of SAT research to global public health, the goal of bringing all SAT labs to a relatively standardized set of expectations, and its ultimate intent to prevent possible bioterrorism attacks and exposures. As biosafety professionals, part of our role is to promote biosecurity despite limited resources and lack of clarity in regards to the SAR. We believe that the future of SAT research itself is at stake if we don't identify a way to ensure that future generations of scientists have the knowledge to pursue this significant aspect of life science research, and that there are competent biosafety professionals available to support it.

ABSA's members are a repository of biological safety expertise; they are an available and essential partner in exploring the current and future state of US SAT. We, the members of ABSA, formally offer our biosafety expertise and our partnership to address the complex underlying issues highlighted by your request for comment. We direct you to our recently submitted position paper to the Oversight and Investigations Subcommittee Chairman Murphy, and Energy and Commerce Committee Members regarding the 16 July 2014 *Centers for Disease Control and Prevention (CDC) Anthrax Lab Incident* Hearing and the General Accounting Office (GAO) Report, *High Containment Laboratories: Recent Incidents of Biosafety Lapses*. We would be honored to meet with you to further discuss these important issues.

Sincerely,



Marian Downing, RBP, CBSP
ABSA President