



March 27, 2024

Submitted Electronically to: <https://www.regulations.gov>

RE: Response to Notice of Proposed Rulemaking on Possession, Use, and Transfer of Select Agents and Toxins; Biennial Review of the List of Select Agents and Toxins (RIN No. 0920-AA71; Docket No. CDC-2020-0024)

To Whom It May Concern:

We write to offer comments in response to the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS) notice of proposed rulemaking on [Possession, Use, and Transfer of Select Agents and Toxins; Biennial Review of the List of Select Agents and Toxins](#)¹ (NPRM) that was published in the Federal Register on January 30, 2024. COGR is an association of over 200 public and private U.S. research universities and affiliated academic medical centers and research institutes. We focus on the impact of federal regulations, policies, and practices on the performance of research conducted at our member institutions, and we advocate for sound, efficient, and effective regulation that safeguards research and minimizes administrative and cost burdens.

COGR and its member institutions recognize the importance of conducting research involving the use of select agents and toxins in a safe and secure manner. We also recognize the need for regulation to this end and support sensible and effective federal requirements aimed at achieving this goal. We appreciate HHS' solicitation of public input on the NPRM and the opportunity to provide comments.

We fully support the NPRM's removal of *Brucella abortus*, *Brucella melitensis*, and *Brucella suis* from the select agent list for the reasons set forth in the NPRM. This removal will facilitate the conduct of research on vaccine development, diagnostic testing, and control measures concerning these agents.

The remainder of this letter sets forth our comments regarding the NPRM's proposed changes to the definition of "release," exemptions for overlap select agents/toxins, and training requirements. These comments are set forth below under the section of the regulations to which they pertain.

¹ 89 FR 5823

Comments

42 CFR Section 73.1, Definition of “Release”:

Release means any of the following:

- (1) An incident resulting in occupational exposure to a select agent or toxin,*
- (2) An incident resulting in animal/plant exposure to a select agent or toxin,*
- (3) The failure of equipment used to contain a select agent or toxin such that it is reasonably anticipated that a select agent or toxin was released,*
- (4) The failure of or breach in personal protective equipment in the presence of a select agent or toxin, or*
- (5) The failure of biosafety procedures such that it is reasonably anticipated that a select agent or toxin was outside of containment.*

COGR and its member institutions are concerned that the proposed definition of “release” is overly broad and fails to provide sufficient clarity to institutions charged with its implementation. First, subsection (3)’s wording is circular in nature and its use of the phrase “reasonably anticipated” results in potentially applying the release designation to circumstances in which a release did not actually occur. Subsection (4) is also overbroad because it assumes that a failure or breach in personal protective equipment (PPE) in the presence of a select agent or toxin is equivalent to a release of, or exposure to, the agent or toxin even though there are often redundant protections in place to prevent exposure/release in just such circumstances. Further, there is no definition of what the phrase “presence of a select agent or toxin means,” and whether it is meant to encompass situations in which the select agent or toxin is being appropriately contained.

Similarly, Subsection (5)’s reference to a failure of biosafety procedures such that “it is reasonably anticipated that a select agent or toxin was outside of containment” is impractically ambiguous. For example, multiple levels of containment are frequently utilized in handling select agents and toxins, but the definition draws no distinction as to whether breach of a single containment device constitutes a release, even when redundant containment devices and facility containment measures were successful in containing the agent.

The overbreadth and ambiguity inherent in this definition of release will lead to unnecessary reporting of events that pose no danger because: 1) no release occurred; or 2) redundant measures prevented the release from causing harm. Such unnecessary reporting, in turn, imposes significant administrative burdens on both institutions and the government agencies that assess the reports. It frequently takes receiving agencies several months to process a release report after it is received, and increased reporting of events that do not actually pose a significant risk may overwhelm the system.

We are particularly concerned that the additional reporting obligations associated with the failure of/breach in PPE under subsection (4). Currently, employees are trained and encouraged to -- and do -- notify internal biosafety personnel of any potential PPE failure. Biosafety personnel then determine if there was a failure, and if so, they perform a risk assessment to determine if there was

an actual exposure, in which case reports are made to the appropriate agency. Expanding reporting requirements to encompass any event that is “reasonably anticipated” to result in a release may have the unintended result of making employees hesitant to report PPE failures to biosafety personnel in the first place.

42 CFR Section 73.6, Exemptions for Overlap Select Agents and Toxins

(a) Clinical or diagnostic laboratories and other entities that possess, use, or transfer an overlap select agent or toxin that is contained in a specimen presented for diagnosis or verification will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

.....

COGR supports this exemption and urges HHS to expand its scope to specifically encompass research laboratories and activities conducted by those laboratories. In this regard, we recommend incorporating the following revisions, shown in bold, italicized typeface:

Clinical or diagnostic laboratories and other entities, ***including research laboratories***, that possess, use, or transfer an overlap select agent or toxin that is contained in a specimen presented for diagnosis or verification ***or utilized for research purposes*** will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

.....

42 CFR Section 73.15, Training

*(a) * * **

(3) Each individual not approved for access to HHS and overlap select agents and toxins by the HHS Secretary or APHIS Administrator whose responsibilities routinely place them in close proximity (e.g., shared laboratory space) to areas where select agents or toxins are transferred, possessed, or used. The training must be based on the particular needs of the individual and risks associated with working near areas where select agents and toxins are handled or stored. The training must also instruct each individual on the notification requirements related to select agents and toxins. Training must be accomplished prior to the individual's close proximity to areas where select agents or toxins are handled or stored and refresher training must be provided annually.

(4) Each individual not approved for access to HHS and overlap select agents and toxins by the HHS Secretary or APHIS Administrator who performs administrative or oversight functions of the facility related to the transfer, possession or use of such agents or toxins on behalf of the entity (e.g., administrative professionals, facility managers, etc.). The training must instruct each individual on the regulatory requirements relevant to their

administrative or oversight functions. The training must also instruct each individual on the notification requirements related to select agents and toxins. Training must be accomplished prior to the individual performing these functions and refresher training must be provided annually.

.....

COGR is concerned that the scope of personnel encompassed by subsections (a)(3) and (4) is so broad and ambiguous that it will make implementation extremely difficult, if not impossible. Subsection (a)(3) calls for the training of individuals “whose responsibilities routinely place them in close proximity (e.g., shared laboratory space) to areas where select agents or toxins are transferred, possessed, or used . . .” Would a person in a laboratory next door to a laboratory in which select agents are used require training? Is training required for personnel who clean common ways adjacent to such laboratories or persons in areas through which shipments of select agents or toxins may pass? HHS should designate with clarity the specific categories of proximate individuals to which training must be provided. We recommend the following language:

Each individual not approved for access to HHS and overlap select agents and toxins by the HHS Secretary or APHIS Administrator whose daily responsibilities place them directly in laboratory space in which select agents or toxins are transferred, possessed, or used.

Similarly, subsection (4) calls for training any individual “who performs administrative or oversight functions of the facility related to the transfer, possession or use of such agents or toxins on behalf of the entity (e.g., administrative professionals, facility managers, etc.)” HHS should definitively specify the classes and duties of personnel to whom such training should be provided. We suggest the following language:

Each individual not approved for access to HHS and overlap select agents and toxins by the HHS Secretary or APHIS Administrator who performs administrative tasks related to ordering, storing, or securing the transfer, possession or use of such agents or toxins on behalf of the entity.

Conclusion

COGR and its member institutions understand the need to ensure that select agents and toxins are possessed, used, and transferred in a safe and secure manner. We appreciate the opportunity to provide comments on the proposed changes to the regulations governing these agents and toxins. We firmly believe that our recommendations will facilitate institutions’ implementation of these regulatory requirements and help to ensure that the regulations better achieve their intended purpose of protecting the users and the public from exposure to these agents.

Should you have any questions regarding these comments, please contact me or Kristin West, COGR's Director of Research Ethics and Compliance at kwest@cogr.edu.

Sincerely,

A handwritten signature in black ink that reads "M. Owens". The signature is written in a cursive style with a large, looped "M" and a stylized "Owens".

Matt Owens
President