



October 16, 2023

White House Office of Science and Technology Policy
1650 Pennsylvania Ave. NW
Washington D.C. 20502

RE: Request for Information on Potential Changes to the Policies



The scientific community needs more clarity and guidance regarding the terms that are currently used in the DURC and P3CO framework that in turn would be used in a unified oversight policy framework for research of concern. For example, the term “reasonably anticipated” must be contextualized and clarified; the scientific community does not have a clear understanding of how this term can be applied to research projects. A potential solution is to clarify that the *goal* of the experiment is the criteria to use for the term “reasonably anticipated.” In addition, institutions need more guidance on what research does and does not require additional scrutiny.

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Recommendation 5: Clarify biosafety level and how lab might need to progress to higher level of biosafety depending on their work.

The scientific community needs more guidance on how experiences with an agent might need to change under which biosafety levels they are operating in. Often, labs will operate under biosafety level 1 or 2 but, in light of outcomes or better understandings of pathogens that are a direct result of their research, they should then be operating under higher levels of biosafety. The ASBMB recommends OSTP explore how labs can easily and quickly assess if the biosafety levels of their labs might need to change depending on their research.

Definition of potential pandemic pathogens (PPP)

Recommendation 6: The scientific community needs clearer guidance on two terms in particular: “moderately virulent” and “highly virulent.” To better determine virulence and potential pandemic-causing abilities of a pathogen, the ASBMB recommends a threshold using the combination of R0, morbidity and mortality measures to determine what pathogens might require additional scrutiny. It is the combination of morbidity and mortality that has implications for pandemic-causing capabilities. In addition, the ASBMB strongly urges OSTP to re-evaluate the PPP definition specifying “respiratory route.” Potential pandemic pathogens are not restricted to respiratory routes of transmission, and narrowing the definition of PPP to respiratory routes of transmission has the potential to miss many PPP.

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The scientific community and researchers need clearer guidance on two terms in particular: “moderately virulent” and “highly virulent.” To better determine virulence and potential pandemic-causing abilities of a pathogen, the ASBMB recommends a threshold using the combination of R0, morbidity and mortality measures to determine what pathogens might require additional scrutiny. It is the combination of morbidity and mortality that has implications for pandemic-causing capabilities. In addition, the ASBMB strongly urges OSTP to re-evaluate the PPP definition specifying “respiratory route.” Potential pandemic pathogens are not restricted to respiratory routes of transmission, and narrowing the definition of PPP to respiratory routes of transmission has the potential to miss many PPP.

In addition, the ASBMB recommends, at the bare minimum, defining PPP should harmonize with the definitions that scientific journals follow. This will ensure uniformity of understanding across the scientific community.

Recommendation 7: An ongoing effort to ensure uniformity of understanding across the scientific community.

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secretary has previously determined a list of