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Ladies and Gentlemen,

The American Biological Safety Association (ABSA) is an international group of biological safety professionals and is known as one of the world's foremost resources on biological safety practices. ABSA has reviewed the proposed revisions to the "NIH Guidelines for Research with Recombinant DNA (NIH Guidelines)" which were announced in the Federal Register on July 25, 2011. We have the following comments to share:

We suggest that OBA update Section II-A-3 of the NIH Guidelines with revision or insertion of information on the Risk Group assignments for the commonly used attenuated strains. Currently this section instructs readers that "Certain attenuated strains or strains that have been demonstrated to have irreversibly lost known virulence factors may qualify for a reduction of the containment level compared to the Risk Group assigned to the parent strain".

OBA should consider adding additional information to Section II-A-3 covering the assignment of Risk Group to commonly used attenuated strains. Suggested text for consideration by OBA for the proposed revision of Appendix B is as follows: "In Appendix B, some of the more commonly used attenuated strains have been assigned to a lower Risk Group classification than the parent strain." The recommended containment level for research uses of these attenuated strains is equal to the Risk Group classification with the exception that BL3 practices should be considered for high concentrations of attenuated strains of *Francisella*.

It is suggested that Appendix B be for Risk Group assignment, and if OBA would like to suggest a containment level like was done with the attenuated *Francisella* strains, then it could be done in Section II-A-3 where the risk assessment process is described and the relationship between Risk Groups and Biosafety Levels is detailed.

We appreciate this opportunity to have provided these comments regarding this proposal.

Sincerely,

Karen Byers, MS, RBP, CBSP  
President  
American Biological Safety Association