



Position Paper—Federal Register

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National Institutes of Health
Office of Biotechnology Activities
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RE: *Federal Register*: August 13, 2001 (Volume 66, Number 156) (Proposal to amend Appendix B-I of the Guidelines to establish criteria for designating strains of *E. coli* as risk group 1 agents)

September 10, 2001

Dear Sirs,

The American Biological Safety Association (ABSA) is an organization of biological safety practitioners who work in a variety of academic, governmental, and private work environments. We have reviewed your Notice of Proposed Action under the National Institute of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules that was published in the August 13, 2001 issue of the *Federal Register*.

We agree with the spirit and intent of the proposed revisions. They are specifically focused on a widely used strain of *Escherichia coli*. We do have two suggestions to clarify the intent of the proposed revisions.

The phrasing “and has a ‘rough’ colony morphology” is not informative. Colony morphology is a phenotypic property dependent on growth conditions—temperature, media, etc.—as well as underlying genotype. For instance, many of the K-12 derived strains, such as *E. coli* JM109 constructed by J. Messing, do not have a “rough” colony morphology due to production of colanic acid and other exopolysaccharides. We would like to suggest that the phrase “and has a ‘rough’ colony morphology” be deleted from the proposed Appendix B revisions. Also, the phrase, “does not carry any genes,” may be overly restrictive. In the Florida case, the investigator may have inactivated virulence factors by partial deletion of sequences. Reversion would be extremely unlikely, yet probes may detect presence of sequences not deleted from the host. Your committee may wish to consider modifying the last sentence of Appendix B to say, “does not carry any [functional genes] or [complete genes] encoding these factors.”

Thank you for the opportunity to have provided these comments. Your efforts to keep these guidelines active and current are appreciated.

Sincerely,

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President, American Biological Safety Association