

**APPENDIX 3:
ENVIRONMENTAL IMPACT**

Claim for Categorical Exemption:

Bio-Rad Laboratories respectfully requests a claim for categorical exclusion under 21 CFR §25.30.

In accordance with the provisions of said chapter, Bio-Rad Laboratories reasonably believes that this petition falls under a categorically excluded class, listed under 21 CFR §25.30(k): 'Establishment or repeal by regulation of labeling requirements for marketed articles if there will be no increase in the existing levels of use or change in the intended uses of the product or its substitutes.'

Therefore, by derogation, an Environmental Assessment or Environmental Impact Statement is not required.