

**Study Plan Amendment**

Change-No: <sup>1</sup>

Major Change <sup>2</sup>

P - / 3425

1

yes  no

**Short Title**

SCoR 2 BRIDGING, Ames

**Study Director**

SWB

**Author of Change**

SWB

**Date Submitted**

13-Feb-2002

**Subject**

Repetition of assay 2

**Reason(s) for Change**

A contamination in strains TA98, TA1535, and TA1537 was observed (UV light resistance, tetracycline resistance). Therefore the data from experimental day 29-Jan-2002 are invalid.

**Change**

Assay/Batch 2 will be completely repeated, including a new test substance preparation during 8th CW 2002 with few deviations: The amount of TPM collected for one batch will be at least 450 mg. The TPM batch will be collected on 3 different glass fiber filters (47 mm diameter). The TPM from the glass fiber filters will be processed together. It will be extracted with dimethyl sulfoxide (DMSO) (8 ml per filter). The proposed experimental period will be the 9th CW 2002.

**Consequences of Change and Measures to be Taken**

All results of Assay/Batch 2, Date of Assay 29-Jan-2002 will be marked as invalid. Assay 2 will be completely repeated.  
Information will be given to team AC.

p.t.o.

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<sup>1</sup> Number is assigned by study director.

<sup>2</sup> Decision by study director