1. Were the submitted test method and supporting validation data subjected to a transparent and independent peer review process?

The validation results have already been published and are included in a Health and Labour Sciences Research Report. Although the developer has published a research paper, no validation study has been published. Our peer evaluation was performed by independent specialists.

2. Does the data generated by the test method adequately measure or predict the end point of interest? For replacement test methods, does the data show a linkage between the proposed test method and an existing test method, and/or the proposed test method and effects in the target or model species?

Evaluation of substances with poor water solubility is stated as a strength, but there is little substantiating data. Approximately 70% agreement was observed. No direct comparison with 3T3–NRU was made.

3. Does the test method generate data useful for hazard/risk assessment purposes?

This test method is useful for hazard assessment but not for risk assessment.

Produces few false negatives but many false positives.

4. Do the submitted test method and supporting validation data adequately cover a spectrum of chemicals and products representative of those administered by the regulatory program or agency for which the test method is proposed? Are the applicability and limitations of the test method clearly described?

Unable to clarify detailed application parameters due to the limited number of substances tested during validation studies.

5. Is the test method sufficiently robust (relatively insensitive to minor changes in protocol) and transferable among properly-equipped laboratories with adequately-trained staff?

Easily transferable.

Unclear as to how robust the test method is against minor changes in protocol.

With the exception of a solar simulator, no special equipment is required.

6. Is the test method both time and cost effective as well as likely to be used in a regulatory context?

Requires time and effort.

Has economic merit.

Few false negatives makes this test method useful for regulatory purposes.

7. Can scientific, ethical, and economic justification be provided for the new or updated test method in light of existing test methods?

Scientific justification comes from the ability to reduce false negatives by combining different indices.

Ethical justification comes from comparison with animal testing.

Economic justification comes from lower costs.

8. Recommendations in favor of the test method

A lack of validation results.

Need for verification using multiple test substances with an established protocol.

Need to substantiate suitability for evaluation of substances with poor water solubility.

Based on the above, the JaCVAM Regulatory Acceptance Board has decided not to propose regulatory use of a combination of yeast growth inhibition and hemolysis testing as an alternative phototoxicity test until the results recommended by the Regulatory Acceptance Board are obtained.