

Appendix A

ICCVAM Evaluation of the BG1Luc ER TA (LUMI-CELL[®]) Test Method – Timeline

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ICCVAM Evaluation Timeline

January 2004	Xenobiotic Detection Systems, Inc. (XDS, Durham, NC) nominates their LUMI-CELL [®] BG1Luc ER TA Test Method for an interlaboratory validation study
April 21, 2004	<i>Federal Register</i> Notice (69 FR 21564) – <i>In Vitro</i> Endocrine Disruptor Test Methods: Request for Comments and Nominations
March 16, 2006	<i>Federal Register</i> Notice (71 FR 13597) - Notice of Availability of a Revised List of Recommended Reference Substances for Validation of <i>In Vitro</i> Estrogen and Androgen Receptor Binding and Transcriptional Activation Assays: Request for Comments and Submission of <i>In Vivo</i> and <i>In Vitro</i> Data
November 27, 2009	<i>Federal Register</i> Notice (74 FR 62317) – Evaluation of <i>In Vitro</i> Estrogen Receptor Transcriptional Activation and <i>In Vitro</i> Cell Proliferation Assays for Endocrine Disruptor Chemical Screening: Request for Nominations for an Independent Expert Peer Review Panel and Submission of Relevant <i>In Vitro</i> and <i>In Vivo</i> Data
January 24, 2011	<i>Federal Register</i> Notice (76 FR 4113) – Announcement of an Independent Scientific Peer Review Panel Meeting on an <i>In Vitro</i> Estrogen Receptor Transcriptional Activation Test Method for Endocrine Disruptor Chemical Screening; Availability of Draft Background Review Document (BRD); Request for Comments
March 29-30, 2011	Independent Scientific Peer Review Panel holds a public meeting, with opportunity for public comments, at Natcher Conference Center in Bethesda, MD. The Panel was charged with reviewing the current validation status of the BG1Luc ER TA test method and commenting on the extent to which the information in the draft BRD supported the draft ICCVAM test method recommendations.
April 26, 2011	<i>Federal Register</i> Notice (76 FR 23323) – Meeting of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM)
May 18, 2011	<i>Federal Register</i> Notice (76 FR 28781) – Independent Scientific Peer Review Panel Report: Evaluation of the Validation Status of an <i>In Vitro</i> Estrogen Receptor Transcriptional Activation Test Method for Endocrine Disruptor Chemical Screening: Notice of Availability and Request for Public Comments
June 16-17, 2011	SACATM public meeting, SACATM and public comments on the draft Panel conclusions and recommendations
August 24, 2011	ICCVAM approves forwarding the test method evaluation report to Federal agencies for consideration.
Fall 2011	Transmittal of ICCVAM recommendations to Federal agencies

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