Evaluation Report on the Stably Transfected Transcription Activation (STTA) assay using the human Estrogen Receptor (ER) α-HeLa-9903 cell line

Hiroshi Ono[1], Tohru Marunouchi[2], Taisen Iguchi[3,4], and Atsushi Ono[5,6]

[1]Hatano Research Institute, Food and Drug Safety Center, [2]Fujita Health University,
[3]National Institute for Basic Biology, [4]Yokohama City University, [5]Okayama University,
[6]National Institute of Health Sciences

Abstract

The Stably Transfected Transcription Activation (STTA) assay using the human Estrogen Receptor (ER) α-HeLa-9903 cell line (ER STTA assay) is an in vitro test that detects estrogen or antiestrogen activity of chemical substances by measuring chemoluminescence and was developed as a means of identifying endocrine disruptors. The ER STTA protocol was developed in Japan by the Chemicals Evaluation and Research Institute (CERI) using the hERα-HeLa-9903 cell line established by Sumitomo Chemical Co. and has been proposed to the OECD through the joint efforts of the Ministry of Health, Labour and Welfare and the Ministry of Economy Trade and Industry. The ER STTA assay was developed as a means of quantitative assessment, and although the agonist test was confirmed by a validation study to be a reliable means of quantitative assessment, the antagonist test was found by a validation study to exhibit considerable variation in quantitative values between participating laboratories. Thus, the ER STTA assay has been adopted in OECD TG 455 as a means of qualitative assessment.

This report presents a summary of the validation report, the peer review report, and OECD test guideline No. 455 as well as an overview of the test itself and the opinions of the Committee.

As a result, the Committee concluded that the ER STTA assay is regulatory acceptable method to screen chemicals on their potential of endocrine disruption via ER, while, the ER STTA assay to be a means of screening methods which can contribute to the regulation of chemical substances when used in combination with other test methods capable of identifying a specific hazard.