Regulatory Acceptance of the BG1Luc Estrogen Receptor Transactivation Test Method

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Abstract

NICEATM coordinated an international interlaboratory validation study of the BG1Luc estrogen receptor transactivation test method (BG1Luc ER TA, LumiCell®) developed by Xenobiotic Detection Systems, Inc. In 2010, the validation study completed its goal to evaluate the usefulness and limitations of the BG1Luc ER TA test method to screen for substances with *in vitro* ER agonist or antagonist activity. The international validation study was sponsored by NICEATM, with participation from the European Centre for the Validation of Alternative Methods, and the Japanese Center for the Validation of Alternative Methods. In 2012, NICEATM–ICCVAM released a test method evaluation report on the usefulness and limitations of the BG1Luc ER TA test method. ICCVAM recommended the use of the BG1Luc ER TA as a screening test to identify substances with *in vitro* ER agonist and antagonist activity and recommended that the BG1Luc ER TA test method could be considered as an alternative to the existing ER TA test guideline (EPA OCSPP 890.1300/OECD TG 455). All 15 ICCVAM member agencies, including the US Environmental Protection Agency, concurred with the ICCVAM recommendations. NICEATM sponsored the new method for evaluation by the Organisation for Economic Co-operation and Development (OECD), which approved the BG1Luc test method and added the BG1 agonist protocol to the existing Test Guideline 455. The BG1 antagonist method has been adopted as OECD Test Guideline 457. Acceptance of the BG1Luc ER TA test method by U.S. and international agencies is an example of increased cooperation and collaboration to support the international adoption of scientifically valid test methods that will protect people, animals, and the environment while reducing, refining, and replacing animal use.