

International Acceptance of In Vitro Alternative Ocular Safety Testing Methods: The Isolated Chicken Eye (ICE) Test Method (draft OECD TG 438)

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The ICE test method is an *in vitro* method that provides short-term maintenance of the chicken eye. Potential ocular damage is assessed by corneal swelling, opacity, and fluorescein retention. ICCVAM recommended that ICE could be used to classify positive substances as ocular corrosives and severe irritants. While not a complete replacement for the *in vivo* rabbit eye test, ICE can be used in a tiered-testing strategy for regulatory classification and labeling within a specific applicability domain. These recommendations were accepted by U.S. Federal agencies, and positive results from ICE may now be used in the U.S. instead of the rabbit eye test for certain regulatory hazard classification decisions. To have the greatest impact on reducing animal use, ICCVAM, with input from stakeholders in the U.S., EU, and Japan, drafted an OECD Test Guideline (TG) that is based on the ICCVAM ICE test method protocol. This protocol was developed following an international peer review evaluation with contributions from ECVAM and JaCVAM. The draft TG 438 was recently accepted by the OECD WNT. Once formally adopted by the OECD Council, TG 438 will be accepted by all 30 OECD member countries in accordance with OECD Mutual Acceptance of Data. The use of ICE will reduce the use of rabbits for eye safety testing and eliminate the *in vivo* testing in animals of most substances likely to cause severe pain and discomfort. ILS staff supported by NIEHS contract N01-ES-35504. The views above do not necessarily represent the official position of any government agency.