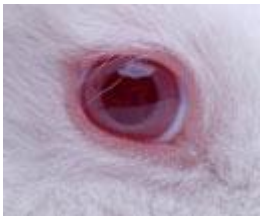
Draize rabbit eye test replacement milestone welcomed



The Dr Hadwen Trust for Humane Research has welcomed the news that international acceptance of non-animal methods to replace the Draize rabbit test for severe eye irritancy, has now been achieved meaning thousands of rabbits will be spared procedures where chemical substances are applied to their eyes[1]. The Dr Hadwen Trust funded early-stage research work in the 1980s that has now resulted in one of the replacement methods approved.

Acceptance by the Organisation for Economic Cooperation and Development (OECD) means that guidance is finally in place on how to conduct the tests without using live rabbits[2]. Two test-tube methods for assessing eye irritation have been accepted by the OECD, the BCOP (Bovine Corneal Opacity and Permeability) test and the ICE (Isolated Chicken Eye) test, both for identifying ocular corrosives and severe irritants.

Whilst the Draize test will continue to be conducted for substances that are not severe eye-irritants, the OECD's decision does mean that many thousands of rabbits will be spared distressing and painful tests that have been scientifically criticised for many decades for poor reproducibility and species differences between rabbits and humans[3]. Some 4,500 rabbits are used in eye irritancy tests in the European Union each year[4]. Global use is likely to be considerably higher.

It has taken at least thirty years for alternative tests to be approved, with research starting in the 1980s, scientific approval by the European Centre for the Validation of Alternative Methods (ECVAM) coming in 2007 and now OECD acceptance in 2009 meaning that the test can be used globally.

"The Draize eye test has been scientifically and ethically discredited for many years," says the Dr Hadwen Trust's Science Director Dr Sebastien Farnaud, *"so to replace it with test-tube methods that produce reliable results and don't cause animal suffering, is very welcome. The Dr Hadwen Trust is proud that its research has been a part of the history of efforts to replace the Draize test, but we sincerely hope that the final chapter in its total replacement will be a far swifter process."*

The Dr Hadwen Trust was one of the first-ever funders to support research to replace the Draize test. In the 1980s DHT-funded innovative research at Leicester Polytechnic resulted in the very first eye irritation test and forerunner of the BCOP test that has now achieved OECD approval[5]. The Dr Hadwen Trust ceased funding research using animal tissues or cells in 1988, but our project represented a turning point in international efforts to replace the Draize test.

It is highly regrettable that it has taken some thirty years to achieve international acceptance of these replacement solutions. Whilst funding, industry support for alternatives and consequently the speed of method development has significantly improved in recent years, unnecessary delays in the validation process remain a problem. A particular issue is that animal test data are still treated as the 'gold standard' against which alternative tests are compared in order to achieve scientific validation. However when animal data are of such poor and variable quality such as the rabbit eye test, the process of replacing scientifically weak animal methods can be delayed by years.

The OECD has also approved a number of other Three Rs (such as refinement and reduction) measures into test guidelines. Through our work as members of test guideline coalition ICAPO, the Dr Hadwen Trust continues to be involved in further test guideline development and we hope to bring you news of more replacement methods in the future.

Notes:

[1] Developed in 1944, the Draize rabbit eye irritation test has been the standard method for evaluating the ocular irritation/corrosion potential of a substance for regulatory purposes. Adult albino rabbits are most commonly used for eye irritancy tests because they have eyes with a large surface area. At least three animals are used per test substance. The test involves applying the substance directly into one eye (the other eye acting as a control) and observing effects for up to 21 days. Effects can include swelling, soreness and weeping eyes.

[2] The OECD adopted the new methods on 7 September 2009

[3] For example Weil & Scala (1971) Toxicol.Appl.Pharmacol. 17,276-360; Freeberg et al. (1986) J. Toxicol.Cut.Ocular Toxicol. 5, 115-123; Koch et al. (1989) J.Toxicol Cut.Ocular Toxicol. 8, 17-22.

[4] Latest statistics available from the European Commission are for 2005

[5] The Dr Hadwen Trust funded Dr Colin Muir, a research fellow at Leicester Polytechnic. Dr Muir developed the 'opacitometer' which shines a light beam through the isolated cornea enabling an objective measurement of changes in its opacity. His publications between 1984 and 1987 are acknowledged as providing the essential groundwork and inspiration for the BCOP test.