ESAC statement on the conclusions of the ICCVAM retrospective study on Organotypic in vitro assays as screening tests to identify potential ocular corrosives and severe irritants as determined by US EPA, EU(R41) and UN GHS classifications in a tiered testing strategy, as part of a weight of evidence approach

At its 26th Meeting, held on 26-27 April 2007 at the European Centre for the Validation of Alternative Methods (ECVAM), Ispra, Italy, the non-Commission members of the ECVAM Scientific Advisory Committee (ESAC)1 unanimously endorsed the following statement:

1. With regard to the results and conclusions from the ICCVAM retrospective study2,3 on:

“Organotypic in vitro assays as screening tests to identify potential ocular corrosives and severe irritants as determined by US EPA, EU(R41) and UN GHS classifications in a tiered testing strategy, as part of a weight of evidence approach”

ESAC endorses the following conclusion:
There are sufficient data to support the use of the Bovine Corneal Opacity and Permeability (BCOP) test method, and the Isolated Chicken Eye (ICE) test method in appropriate circumstances and with certain limitations3, as screening tests to identify substances as ocular corrosives and severe irritants in a tiered-testing strategy, as part of a weight-of-evidence approach.

2. With regard to the Isolated Rabbit Eye assay (IRE) and the Hen’s Egg Test – Chorio-Allantoic Membrane assay (HET-CAM), ESAC recommends that further work should be performed before a statement on their validity can be made.

It should be noted, however, that European authorities previously stated that while all four tests were not yet validated, positive outcomes from these tests could be used as the basis for classifying and labelling substances as severe eye irritants (R41)4.

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27 April 2007
1. The ESAC was established by the European Commission, and is composed of nominees from the EU Members States, industry, academia and animal welfare, together with representatives of the relevant Commission services.

This statement was endorsed by the following members of the ESAC:

Ms Sonja Beken (Belgium)
Ms Dagmar Jiřová (Czech Republic)
Mr Tõnu Püssa (Estonia)
Mr Lionel Larue (France)
Mr Manfred Liebsch (Germany)
Ms Annalaura Stamma ti (Italy)
Mr Jan van der Valk (The Netherlands)
Mr Constantin Mircioiu (Romania)
Mr Albert Breier (Slovakia)
Ms Argelia Castaño (Spain)
Mr Patric Amcoff (Sweden)
Mr Jon Richmond (UK)
Mr Carl Westmoreland (COLIPA)
Ms Vera Rogiers (ECOPA)
Ms Nathalie Alépée (EFPIA)
Mr Robert Combes (ESTIV)
Mr Hasso Seibert (European Science Foundation)

The following Commission Services and Observer Organisations were involved in the consultation process, but not in the endorsement process itself.

Mr Thomas Hartung (ECVAM; chairman)
Mr Jens Linge (ECVAM; ESAC secretary)
Ms Susanna Louhimies (DG Environment)
Ms Barbara Mentré (DG ENTR)
Ms Grace Patlewicz (ECB, DG JRC)
Mr Christian Wimmer (DG Research)
Mr Hajime Kojima (JACVAM)
Ms Laurence Musset (OECD)
Mr Barry Philips (Eurogroup for Animal Welfare)
Mr William Stokes (NICEATM, USA)

2. “Background Review Documents on In vitro test methods for detecting ocular corrosives and severe irritants”:
   - Bovine Corneal Opacity and Permeability test;
   - Isolated Rabbit Eye test;
   - Hen’s Egg Test – Chorio-Allantoic Membrane test;
   - Isolated Chicken Eye test.

Website: http://iccvam.niehs.nih.gov/methods/ocutox/ivocutox/ocu_brd.htm

