



EUROPEAN COMMISSION
DIRECTORATE GENERAL JRC
JOINT RESEARCH CENTRE
Institute for Health and Consumer Protection
European Centre for the Validation of Alternative Methods (ECVAM)

STATEMENT ON THE SCIENTIFIC VALIDITY OF THE *IN VITRO* MICRONUCLEUS TEST AS AN ALTERNATIVE TO THE *IN VITRO* CHROMOSOME ABERRATION ASSAY FOR GENOTOXICITY TESTING

At its 25th Meeting, held on 16-17 November 2006 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:

On the basis of a peer review² of a weight-of-evidence retrospective validation³, the Committee endorses the conclusion that the *in vitro* micronucleus test (MNT) is a scientifically valid alternative to the *in vitro* chromosome aberration (CA) assay for genotoxicity testing.

To facilitate test guideline development and regulatory acceptance, a standardised test protocol and performance standards need to be defined. The *in vitro* MNT can then be considered for regulatory use as part of the tier 1 genotoxicity test battery.

The Committee recommends that the follow-up actions documented in the peer review report² are addressed by the Validation Management Team (VMT) and during discussions on the OECD draft test guideline 487.⁴

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17 November 2006

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:

Mr Walter Pfaller (Austria)
Ms Sonja Beken (Belgium)
Ms Dagmar Jírová (Czech Republic)
Ms Elisabeth Knudsen (Denmark)
Mr Tõnu Püssa (Estonia)
Mr Timo Ylikomi (Finland)
Mr Manfred Liebsch (Germany)
Mr Efstathios Nikolaidis (Greece)
Ms Katalin Horvath (Hungary)
Ms Annalaura Stammati (Italy)
Ms Maija Dambrova (Latvia)
Mr Jan van der Valk (The Netherlands)
Mr Dariusz Sladowski (Poland)
Mr Albert Breier (Slovakia)
Mr Jon Richmond (UK)
Ms Odile de Silva (COLIPA)
Ms Julia Fentem (ECETOC)
Ms Nathalie Alépée (EFPIA)
Mr Robert Combes (ESTIV)
Ms Maggy Jennings (Eurogroup for Animal Welfare)
Mr Roman Kolar (Eurogroup for Animal Welfare)

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 Elke Anklam (Director of IHCP)
Mr Juan Riego Sintes (ECB)
Mr Siegfried Breier (DG Enterprise, Unit F.3)
Ms Susanna Louhimies (DG Environment, Unit C.3)
Ms Beatrice Lucaroni (DG Research, Unit F.5)
Mr Christian Wimmer (DG Research)
Mr Constantin Mircioiu (Romania)
Mr Len Schechtman (ICCVAM, USA)
Mr William Stokes (NICEATM, USA)
Ms Vera Rogiers (ECOPA)
Mr Hasso Seibert (European Science Foundation)

2. *ESAC Peer Review - Retrospective Validation of the In Vitro Micronucleus Test: Summary & Conclusions of the Peer Review Panel*, 10pp., October 2006.
3. Albertini, S., van Benthem, J., Corvi, R., Hoffmann, S., Maurici, D., Pfuhler, S. & Vanparys, P. (2006) *Report on Micronucleus Test (MNT) In Vitro*. 61pp. ECVAM.
4. OECD (2004) *OECD Guideline for the Testing of Chemicals. Draft Proposal for a New Guideline 487. In Vitro Micronucleus Test*, 1st version, June 14, 2004. 13pp. OECD, Paris.