Cooperation with the OECD and Strategies for Replacing Animal Procedures – OECD TestGuidelines

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The Organisation for Economic Co-operation and Development (OECD) is an inter-governmental organisation in which representatives of 30 industrialised countries meet to co-ordinate and harmonise policies and work together to respond to international problems. The OECD Test Guidelines (TG), that are developed by the Test Guidelines Programme (TGP) of the Environment, Health and Safety Division, are a collection of the most relevant internationally agreed test methods used by government, industry and others to assess the safety of chemical products for the protection of man and the environment[1]. The work is overseen by the Working Group of National Co-ordinators of the TGP (WNT) and dependent on member countries active participation in the projects and long-term commitments to the development and validation of new alternative test methods. Animal welfare, and adherence to the 3R-principles as laid down by Russell & Burch in 1959, is always considered when existing TGs are revised and when new test methods are being developed.

To facilitate alternative test method development and their regulatory acceptance, OECD has developed a Guidance Document No. 34 (GD 34) on "*the Validation and International Acceptance of New or Updated Test Methods for Hazard Assessment*"[2], based on internationally acclaimed validation and regulatory acceptance principles. These principles are now requirements for all new or updated TGs. New tailored validation concepts for specific applications, such as Performance-Based TGs, are under evaluation by the Validation Management Group for Non-Animal tests (VMG NA) that oversees the development of new *in vitro* TGs for the testing of chemicals with potential endocrine disruptive properties. Following the adoption of GD 34 in 2005, Performance Standards (PS) have become commonly used for new *in vitro* TGs, *e.g,* for the TG 435 on "*In Vitro* Membrane Barrier Test Method for Skin Corrosion" and the newly adopted TG 437 "*Bovine Corneal Opacity test*" (BCOP) and TG 438 "*Isolated Chicken Eye test"* (ICE) for identification of severe eye irritants. PS are also suggested to be incorporated into the new draft TG for *in vitro* skin irritation and the existing TGs 430 and 431 on skin corrosion as well as into the revised Local Lymph Node Assay (TG 429). The PS will provide means for developing proprietary test methods into TGs and the development of similar "me-too tests". Implementation of the OECD principles of validation and regulatory acceptance enhances international harmonisation of validation of alternatives, saves resources and animals and facilitates international collaborations and adoption of OECD TGs.

The German Federal Institute for Risk Assessment (BfR) and the Centre for Documentation and Evaluation of Alternatives to Animal Experiments (ZEBET) is acknowledged for its long-standing commitment and deep engagement in OECD work for the development of new alternative test methods for regulatory uses. Several new TGs that are based on projects lead by Germany, or in collaboration with other member countries, and that have been developed and validated by BfR-ZEBET have been adopted in the last decade. This include alternative Test Guidelines for acute oral (TG 423) and acute inhalation (TG 436) toxicity testing, eye irritation (TG 405), *in vitro* skin corrosion (TG 430, TG 431), skin irritation (TG 404), *in vivo* and *in vitro* skin absorption (TG 427, TG 428) and *in vitro* phototoxicity (TG 432) test method, in addition to having hosted several OECD Expert Consultation Meetings, *e.g.* for the finalisation of the GD 34. The OECD TGP looks forward to future fruitful collaborations with Germany and the BfR-ZEBET on new interesting alternative test methods, and congratulates BfR-ZEBET to its 20 years of successful development of alternative Test Guidelines for the regulatory community.