

Activities to accelerate the recognition procedure for alternative methods to animal experiments by the EU and OECD

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For 20 years the Centre for Documentation and Evaluation of Alternatives to Animal Experiments (ZEBET) within the Federal Institute for Risk Assessment (BfR) has made every effort to reduce the number of animal experiments. ZEBET is also involved in the elaboration of new laws and EU Directives. One important task is the experimental validation of methods involving no laboratory animals for the purposes of their inclusion in international public authority test guidelines in the field of safety toxicology. The most important international organisation involved in the recognition of alternative methods to animal experiments is the Organisation for Economic Co-operation and Development (OECD). Results obtained with OECD test methods are accepted across the globe and are promptly recognised by OECD Member States. However, the OECD recommendations for the recognition of alternative methods to animal experiments must be adopted unanimously. Because of this principle of consensus, which is based on a multi-phase deliberation, feedback and decision-making process, several years may elapse between the submission of the application and recognition and recommendation of the method by the OECD.

With the introduction of the new European chemicals legislation REACH, according to which approximately 30,000 existing chemicals are to be tested retrospectively for their health impact, an increase in animal experiments is to be expected over the next few years. Against this backdrop the EU Member States wish to accelerate the procedure for the recognition of alternative methods. To cater for exceptions which may engender delays in the OECD process, the European Commission has now adopted its own recognition procedure. It envisages the option of the adoption of a majority recommendation for alternative methods within a period of five months. In turn, OECD has indicated its willingness to accommodate as far as possible the accelerated EU procedure.

In this article BfR provides information on the existing OECD procedure for the recognition of alternative methods to animal experiments and the new EU procedure that speeds up this process.

The full version of the BfR Opinion in German is available on http://www.bfr.bund.de/cm/244/aktivitaeten_zur_Beschleunigung_der_anerkennungsverfahren_fuer_alternativmethoden_zum_tierversuch_durch_die_eu_und_oecd.pdf