

Aktuelle Teststrategien und Testrichtlinien “REACH and beyond, but not beyond reach”

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With the instrument of Annex XI, REACH foresees the possible adaptation of the standard testing regime by the use of a wide spectrum of information sources within, if appropriate, a weight of evidence approach. Notably, Annex XI allows the use of so-called “suitable” alternative methods (AMs) which are those that at least fulfil internationally accepted criteria (e.g. the ECVAM’s prevalidation criteria). If such methods are validated, sufficiently documented and suitable for classification and labelling/risk assessment, they may be used for the identification of both negatives and positives. Thus Annex XI provides, potentially, a radical departure from the previous practice of rigid canons of methods for hazard testing and allows the use of recently validated methods that have not reached regulatory level.

ECVAM played an active role in the implementation of the testing guidance for REACH: in 2005 ECVAM was charged (on behalf of the Commission) with steering the development of REACH testing strategies (i.e. strategies to fulfil the information requirements) with the implementation project 3.3 (guidance for industry). ECVAM chaired the stakeholder expert group and the endpoint working group of topical toxicity and participated in the drafting group that finalised the RIP 3.3 product.

In response to this rapidly changing legal environment, ECVAM is continuing to refine its processes. In 2004 ECVAM introduced the Modular Approach to validation which allows fulfilling the information requirements of a validation study in a more flexible manner. At present ECVAM is implementing a Commission reference laboratory for the validation, evaluation and assessment of AM (“CORRELATE”), which is foreseen to mainly handle similar or so-called “me-too” methods, i.e. AMs that resemble already validated methods in both design and objective.

With both measures ECVAM responds to the need of speeding up the validation process to pipeline AMs more effectively while maintaining scientific rigour. The possible flexibility with regard to how information requirements are fulfilled under REACH, however, will only work if data review and decision-making are geared to deal with very heterogeneous sets of data. Thus, structured means of information appraisal and data review as well as efficient means of data integration and internationally agreed and consistent frameworks for transparent decision-making are called for. ECVAM is currently launching an initiative towards Evidence Based Toxicology (EBT) with the first international forum towards EBT held in October this year (<http://www.ebtox.org>). The aim of EBT is to assess the use of evidence-based logic and tools of structured data review and statistical analysis (critical appraisals, systematic reviews and meta analysis) as well as frameworks of decision-making for the purposes of a modern toxicology that is ready to deal with the assessment of risks of an increasingly diversifying nature.