Workshop on acceleration of the validation and regulatory acceptance of alternative methods and implementation of testing strategies - DTU Orbit (08/04/2018)

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This report describes the proceedings of the BfR-RIVM workshop on validation of alternative methods which was held 23 and 24 March 2017 in Berlin, Germany. Stakeholders from governmental agencies, regulatory authorities, universities, industry and the OECD were invited to discuss current problems concerning the regulatory acceptance and implementation of alternative test methods and testing strategies, with the aim to develop feasible solutions. Classical validation of alternative methods usually involves one to one comparison with the gold standard animal study. This approach suffers from the reductionist nature of an alternative test as compared to the animal study as well as from the animal study being considered as the gold standard. Modern approaches combine individual alternatives into testing strategies, for which integrated and defined approaches are emerging at OECD. Furthermore, progress in mechanistic toxicology, e.g. through the adverse outcome pathway approach, and in computational systems toxicology allows integration of alternative test battery results into toxicity predictions that are more fine-tuned to the human situation. The road towards transition to a mechanistically-based human-focused hazard and risk assessment of chemicals requires an open mind towards stepping away from the animal study as the gold standard and defining human biologically based regulatory requirements for human hazard and risk assessment.