



EUROPEAN COMMISSION
JOINT RESEARCH CENTRE

Institute for Health and Consumer Protection
European Union Reference Laboratory for Alternatives to animal testing (EURL ECVAM)

Executive Summary of the first Meeting of the Preliminary Assessment of Regulatory Relevance (PARERE) Advisory Group

A first meeting of the PARERE was held on 26 May 2011 at the Institute for Health and Consumer Protection (IHCP), JRC, Ispra, Italy. Following the adoption of the Directive on the protection of animals used for scientific purposes (2010/63), Member States had been invited by the Commission to nominate representatives for the network, also including representatives from EU regulatory agencies and other Commission DGs. Representatives from both Member States and EC regulatory bodies/agencies, convened at the first meeting, together constituting the PARERE. The meeting was focused on the overall tasks of PARERE in expediting the process of regulatory acceptance of alternative methods by involving regulators as early as possible in the process of development of alternatives; including the following tasks:

- To assess the regulatory relevance, across different regulatory frameworks, of new alternative methods proposed for validation
- To facilitate timely information flow from/to regulators in relation to alternative methods under development and taking account of the respective regulatory needs during validation
- To allow early awareness and buy-in for alternative methods in the pipeline.

ECVAM presented its mission, validation processes, advisory structure of the ECVAM Scientific Advisory Committee (ESAC) and the work programme including on-going validation studies and test method submissions. Four test method submissions were presented to the meeting for discussion of the level of information needed for the PARERE to provide preliminary assessments of their potential regulatory relevance and it was agreed that the submissions should be sent to PARERE for an opinion. It was further described that the expected operational procedures of the PARERE would be via a virtual network and the platform for information exchange would be set up after the meeting, however, it was also proposed to have at least one annual meeting of PARERE to review progress made and operational procedures.