Executive Summary of the first Joint Meeting of the EURL ECVAM Advisory Body on Preliminary Assessment of Regulatory Relevance (PARERE) and the EURL ECVAM Stakeholder Forum (ESTAF)

A first joint meeting of PARERE and the ESTAF networks was held on 25-26 September 2012 at the Institute for Health and Consumer Protection (IHCP), JRC, Ispra, Italy. The first day of the meeting was dedicated to updates on EURL ECVAM activities and the presentation of EURL ECVAM outline strategies for the areas of skin sensitisation, endocrine disruption, potency and safety testing of vaccines, carcinogenicity and toxicokinetics. The second day focused on discussing the roles and commitments of PARERE and ESTAF, how best to collaborate, and how to practically plan upcoming activities and meetings. Other topics that were briefly covered included how to design Integrated Testing Strategies (ITS) based on understanding toxicological modes-of-action, what factors determine the regulatory relevance of alternative methods, and what aspects need to be assured to gain acceptance by decision makers. The following follow-up activities were recommended by the meeting:

- EURL ECVAM should progress with the definition of a strategy implementation plan in the area of skin sensitisation, including establishing a database that will aid in the design and evaluation of ITS, drafting of guidance for various ITS approaches, and how to efficiently engage with the relevant bodies within the OECD to ensure that the development of Test Guidelines for validated methods is compatible with an ITS framework.
- Consultation between EURL ECVAM and the PARERE and ESTAF networks should include strategic and high level issues such as strategy formulation, the use of data/information derived from alternative methods in decision making for safety assessment, dissemination and promotion of alternative methods, progressive approaches to validation and support in the drafting of EURL ECVAM Recommendations.
- -EURL ECVAM should ensure that summary information on test submissions, evaluations and prioritisations is made available through improvements of the current TSAR information system to include more detailed information on the status of methods under validation and/or evaluation, in addition to providing a general 12 month work plan for the networks.

The next meeting of the PARERE and ESTAF networks will be held on 4-6 June 2013 in Ispra, Italy where a one day dedicated workshop on the theme "Establishing the Relevance and Ensuring the Acceptance of Alternative Methods for regulatory Safety Assessment", will be held.