

**Introductory text on the EU-ANSA Research Cluster:
Innovative 3Rs (Replacement, Reduction and Refinement of animal testing)
approaches for the prediction of properties of chemicals, cosmetic ingredients,
medicines, environmental contaminants and other regulated products**

Chemicals and other products containing chemicals might harm human health or the environment. To assess the risk from using chemicals, we need to predict what effects they may have. For forecasting adverse health effects we have traditionally used animals to model effects on humans. For a long time there has been an ethical concern with using experimental animals in this way. The '3Rs' (i.e. Replacement, Reduction and Refinement of animal testing) is a structured approach to minimise and eventually eliminate using animals. Other evidence can be used instead of animal studies to model toxic effects in humans. Some *in vitro* tests (i.e. laboratory studies) are a one-for-one replacement of an individual animal test. However, complex adverse effects, such as toxicity resulting from prolonged exposure to chemicals, are much more challenging to deal with. The latest developments in science help in understanding the underlying biology of what is happening when humans are exposed to toxicants. This enhanced theoretical knowledge is occurring at the same time as sophisticated new scientific tools are being developed, so-called 'new approach methods', that contribute synergistically to this understanding. This has led to approaches to combine different lines of evidence.

The topic of this Research Cluster is highly relevant in Europe. Animal welfare and reducing and eventually replacing experimental animals is important to EU citizens. This is reflected in legislation, e.g. the EU Cosmetics Regulation bans animal testing of cosmetics and their ingredients, yet these products must still be assessed to confirm they are safe when used. Another key priority for the EU is protecting human health and the environment, and the EU leads the world in chemical safety control. The Registration, Evaluation and Authorisation of Chemicals Regulation (the so-called REACH Regulation) requires industry to register all chemical substances that are made or imported at 1 tonne per annum with information on their toxicological, environmental and chemical properties. This information on over 21,000 substances is disseminated, and is an invaluable resource for researchers. These joint European concerns with safety of chemicals and animal welfare mean there is a high motivation for researching and developing new techniques and approaches for assessing chemicals and products containing chemicals. This is reflected by the activities and work of various EU institutions, notably the JRC (especially the IHCP and EURL ECVAM) and the EU Research and Innovation programme (currently 'Horizon 2020').

Several EU-ANSA agencies are involved in safety assessment of chemicals and products containing chemicals, so are interested in communicating R&D needs for better non-animal tests and approaches. The '3R's research cluster' was prepared by ECHA, EFSA, EMA and the SANTE scientific committees SCCS/SCHEER in consultation with the JRC-IHCP.