



Statement on Horizon 2020 & Funding a 'Human Toxicology Project'

The Human Toxicology Project Consortium is a multi-stakeholder coalition drawn from the corporate, academic and civil society communities, working to accelerate the global implementation of an innovative, non-animal approach to chemical and product safety testing and risk assessment. The goals are to advance human health and environmental protection, create job growth and innovation, and move away from animal testing. Based on an understanding of biological 'pathways' of disease and toxicity in humans, i.e. how chemicals disrupt normal body functions at the cellular level, this sophisticated new approach has the potential to produce human-relevant data more efficiently and economically than is possible with animal testing. With better data comes improved regulatory decision-making, including the ability to deal more effectively with emerging challenges such as risk assessment of chemical mixtures, nanomaterials, and suspected endocrine-active chemicals.

BACKGROUND

In 2007, the U.S. National Academy of Sciences identified the need for a fundamental change in the way safety testing is carried out, envisioning "... a not-so-distant future in which virtually all routine toxicity testing would be conducted in human cells or cell lines *in vitro*...". The technology needed for this transformation is already available or in advanced development. What has been missing to date is a commitment from key innovation economies to a global 'Human Toxicology Project'—a coordinated multi-national research and development effort akin to the Human Genome Project, with clear goals and adequate resources.

The EU FP7 project AXLR8 (axlr8.eu) has endorsed this approach as a priority for future EU research in the context of Horizon 2020, recommending an investment of not less than 325 million € as part of public-private partnership with regulated industry and public-public partnerships with other innovation economies. An initial framework for coordinating such a large-scale effort is already in development in the context of the OECD 'Adverse Outcome Pathway' work programme.

STATEMENT

Members of the Human Toxicology Project Consortium are key players in the innovation chain for chemicals, medicines and consumer products. We endorse the AXLR8 recommendations, and the positions of Humane Society International on advancing a new paradigm in safety testing, and urge the EU to ring-fence substantial resources under Horizon 2020 and beyond for an 'innovation flagship' initiative aimed at:

1. Elucidation of 'adverse outcome pathways' relevant to safety testing and health research
2. Development of human biology-based cellular and molecular tests and other key enabling technologies to detect perturbations of these biological pathways
3. Development of next-generation computational, systems biology, pharmacokinetic and related bioinformatic tools to relate mechanistic *in vitro* data to a whole-body scenario.
4. Creation of the decision tools to apply this information in risk and safety assessments.

Such a multinational and multidisciplinary research effort requires a careful strategic focus and 'top-down' coordination, which can best be achieved through formal collaborative research agreements, e.g. with the heads of U.S. agencies engaged in the 'Tox21' collaboration. This will maximise the potential for synergies arising from international cooperation while enabling the EU to meet its specific policy needs and maintain its longstanding leadership position in this rapidly evolving research area.

Members of the Human Toxicology Project Consortium include Dow, DuPont, ExxonMobil, The Hamner Institutes for Health Sciences, Humane Society International, Humane Society Legislative Fund, The Humane Society of the United States, the Johns Hopkins University Center for Alternatives to Animal Testing, Johnson & Johnson, L'Oréal, Procter & Gamble, and Unilever.