

Human Toxicology Project Consortium

To facilitate the global shift to a cell response pathway paradigm for chemical safety assessments, which holds great promise for more rapid predictions of human outcomes while superceding traditional animal testing for environmental agents and pharmaceuticals.

Why is a Consortium needed?

No organization has yet stepped forward to mobilize diverse stakeholders and find the support necessary to bring the National Academy of Sciences' (NAS) vision for toxicity testing to life. US Agency efforts, e.g. ToxCast and Tox21, propose simply to augment animal toxicity studies with toxicity pathway assays or use assay results to prioritize animal testing. In contrast, we have developed a multi-stakeholder consortium to lead the early steps in the transformation of toxicity testing for human health risk assessment. A broad, public-private consortium has many advantages.

- Current federal programs fall short of embracing the main NAS recommendations
- Extramural talents and good ideas are synergistic with those found in federal agencies
- Healthy competition moves programs along more quickly – e.g., Human Genome Project
- Private-public programs can speed innovation of outcome-based programs

What would the Consortium accomplish?

- Facilitate the global implementation of the recommendations of the NAS report, by working with multiple stakeholders in academia, industry, government and NGOs

- Promote dialogue, information sharing and establishment of a Research and Development roadmap
- Lobby for, coordinate and provide resources to support transatlantic efforts necessary to fulfill the vision of the NAS report
- Engage in collaborative outreach to legislative, regulatory, corporate, academic and public interest audiences
- Urgently develop a targeted research effort to jump-start the transformation

How would a Consortium Research Program accelerate progress?

- Develop a series of prototypes/case studies to demonstrate the NAS vision in action
- Conduct toxicity testing using cells or cell lines to evaluate how chemicals perturb biological pathways
- Develop next generation tools to interpret results for human risk assessment
- Propose pathway-based risk assessments for these prototypes
- Use initial successes to guide refinement of the NAS vision within the first 5 years
- Engage stakeholder communities as new approaches are developed



The 2007 National Academy of Sciences (NAS) report, *Toxicity Testing in the 21st Century, A Vision and a Strategy*, envisions a major program in the scientific community to advance the science of toxicity testing and to put it on a forward trajectory toward implementation into everyday practice. The change will generate better data on the potential risks to humans posed by exposure to environmental agents and assess chemicals much more efficiently. A stronger scientific foundation offers the prospect of improved risk-based regulatory decisions and greater public confidence in the decisions.

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What are the benefits of new approaches in toxicity testing?

- Significantly reduced number of animals
- Lower costs and less time required
- Broader coverage of chemicals, health effects, life stages and mixtures
- More relevant health risk assessments based on human biology
- Better use of toxicity testing for U.S. legislative initiatives – Toxic Substances Control Act, Federal Insecticide Fungicide and Rodenticide Act and Federal Food Drug and Cosmetic Act; REACH in Europe
- Optimization of government research and development investment

Why place the Consortium Research Program at The Hamner Institutes for Health Sciences?

- Non-profit research organization in Research Triangle Park, North Carolina
- Programmatic initiatives closely link government agencies, academic institutions, industry and NGOs
- 35 years of experience using research for risk and safety-based decision-making
- Director of The Hamner Program in Chemical Safety Sciences served on NAS Committee

- Close ties to Tox21 partners – Environmental Protection Agency, NIH Chemical Genomics Center and National Toxicology Program
- Ongoing projects mirror the NAS vision
- Already home to The Hamner–University of North Carolina Center for Drug Safety Sciences

The Human Toxicology Project Consortium

The Humane Society of the United States (HSUS) and its affiliates, the the Humane Society Legislative Fund (HSLF) and Humane Society International (HSI), have now taken the first steps to enlist partners to a broad multi-stakeholder Consortium. The participants in the planning stages include:

- Dow
- DuPont
- Exxon-Mobil
- HSI
- HSLF
- HSUS
- Johnson & Johnson
- The Procter & Gamble Company
- Unilever

The Consortium is actively engaging other stakeholders in the corporate, academic and public interest communities to rapidly achieve broad membership and support for the Human Toxicology Project.

What do we need to get this program started?

- Support for a research and implementation endeavor by U.S. Congress and stakeholders
- Strategic research program will require ~\$15 M/year for 5 years
 - Asking for \$10 M/year for 5 years from Federal Appropriations
 - Asking for \$5 M/year for 5 years from Consortium and other non-U.S. federal government sources



The Humane Society of the United States is the nation's largest animal protection organization — backed by 11 million Americans, or one in every 28. For more than a half-century, The HSUS has been fighting for the protection of all animals through advocacy, education, and hands-on programs. Celebrating animals and confronting cruelty — On the web at HumaneSociety.org.



The Humane Society Legislative Fund is a social welfare organization incorporated under section 501(c)(4) of the Internal Revenue Code and formed in 2004 as a separate lobbying affiliate of The Humane Society of the United States. The HSLF works to pass animal protection laws at the state and federal level, to educate the public about animal protection issues, and to support humane candidates for office. On the web at HSLF.org.



Humane Society International is the international arm of The HSUS, with offices in Australia, Canada, China, Costa Rica, Europe, India and the United States. HSI has been selected by the European Commission to lead a multi-year, pan-European project called "AXLR8" to accelerate the transition to a toxicity pathway-based paradigm for chemical safety assessment. On the web at HSIEurope.org.