Call for a new approach to toxicity testing & risk assessment to move away from animal use & better protect health, safety & the environment

Rome, August 2009

Whereas animal-based toxicity tests are often decades old, time-consuming, expensive, seldom formally validated, of questionable reliability and relevance scientifically, and responsible for the suffering and death of millions of animals annually;

Whereas the scientific limitations of animal tests are clearly evident in the current 92% failure rate for new drugs (due to safety concerns and inefficacy observed in human trials yet unforeseen in animal studies[1]), while practical considerations preclude reliance upon animal tests to clear the backlog of tens of thousands of existing chemicals to be adequately safety tested;

Whereas recent years have seen unprecedented scientific and technological advances, which hold great promise for advancing the scientific foundation of toxicity testing and risk assessment[2];

Whereas leading scientists from Europe and North America have called for a move away from conventional animal tests in favour of a "21st century" approach based on sophisticated cellular and computational methods that assess chemicals' effects on critical biological processes[3];

Whereas available human data, e.g. from clinical drug trials, represent the "gold standard" for human safety assessment and if made widely available would further the development and evaluation of 21st century approaches.

Whereas initial work along these lines has already begun in certain regions, including the Tox21 Program in the US, various Framework Programme projects in the EU, and the ASAT program in The Netherlands.

Whereas a fundamental paradigm shift in toxicological risk assessment will require a higher level of investment in a sustained, co-ordinated international research and development effort on par with the Human Genome Project of the 1990s.

Therefore, be it resolved that the undersigned call upon governments, regulators, corporations, academic scientists, public interest NGOs, and other stakeholders to actively and cooperatively support a global transition to a humane 21st century approach[3] in toxicological risk assessment in the interests of generating data more relevant to evaluate health risks to people, generating data on a larger number of substances and mixtures, reducing testing costs, while progressively replacing animal testing.

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[1] US FDA (2004). *Challenge and Opportunity on the Critical Path to New Medical Products*. Washington, DC.

[2] EPAA (2008). *New Perspectives on Safety – Workshop Report*. Brussels.

[3] US National Research Council (2007). *Toxicity Testing in the 21st Century: A Vision and a Strategy*. Washington, DC.