

U.S. EPA – U. S. Environmental Protection Agency
Meeting the Needs of a Paradigm Shift: A Regulatory Perspective

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EPA has identified the need to move to a new risk assessment paradigm to increase the speed with which toxicity assessments can be performed while reducing both the cost of testing, the use of animals, and also efficiently identifying and generating focused data for risk assessment. The challenge is to develop a scientific basis to determine what specific data, for which chemicals and which exposures, are essential for the appropriate assessment and management of risks in order to build an efficient and economical test regimen. This requires a combination of scientific/technology activities as well as political and program management activities to obtain regulatory acceptance. Activating a paradigm shift will require sustained effort over many years. Some efforts will require many years, such as research to enhance the interpretation of data, and others can be done in the near- and mid-term, such as guideline revision. To ensure regulatory acceptance of alternatives to current approaches we must clearly articulate their utility and develop public confidence that the approaches are protective of public and environmental health. Successful implementation will require partnerships between scientists and program managers across the international community to coordinate the scientific advances with the evolution of regulatory programs from animal intensive to alternative testing paradigms.