

Workshop on Acute Chemical Safety Testing: Advancing *In Vitro* Approaches and Humane Endpoints for Systemic Toxicity Evaluations
February 6 – 7, 2008

Selected Background References

Public Health and Human Poisonings

Bronstein AC, Spyker DA, Cantilena LR, Green J, Rumack BH, Heard, SE. 2006. Annual Report of the American Association of Poison Control Centers' National Poison data System (NPDS). Clin Toxicol 45:815–917.

<http://www.aapcc.org/Annual%20Reports/06Report/2006%20Annual%20Report%20Final.pdf> [accessed 22 January 2008].

IOM. 2004. Forging a Poison Prevention and Control System. Washington, DC: National Academies Press. Available: <http://www.nap.edu/catalog/10971.html> [accessed 22 January 2008].

Lai MW, Klein-Schwartz W, Rodgers GC, Abrams JY, Haber DA, Bronstein AC, Wruk KM. 2006. 2005 Annual Report of the American Association of Poison Control Centers' National Poisoning and Exposure Database. Clin Toxicol 44:803–932.

<http://www.aapcc.org/Annual%20Reports/05report/2005%20Publsihed.pdf> [accessed 22 January 2008].

Collecting Biomarker Information: Methodologies and Selected Readings

Center for Biomarker Analysis, University of Tennessee, Knoxville. <http://cba.bio.utk.edu/>

International Life Sciences Institute (ILSI) Health and Environmental Sciences Institute (HESI). Development and Application of Biomarkers of Toxicity.

<http://www.hesiglobal.org/Committees/TechnicalCommittees/Biomarkers/>

Marusina K. 2006. Safety Biomarkers Holy Grail of Toxicology: Firms Develop New Technologies, Big Pharma Collaborates, & the FDA Stresses Predictive Tests. Genetic Engineering and Biotechnology News. Oct 15. Vol. 26. No. 18.

<http://www.genengnews.com/articles/chitem.aspx?aid=1920&chid=2>

Molecular Biometrics. 2007. Metabolomic Profiling of Biomarkers.

<http://www.molecularbiometrics.com/machine.html>

NIH. 2001. Biomarkers and Clinical Endpoints in Pediatric Clinical Trials

<http://grants.nih.gov/grants/guide/pa-files/PA-01-043.html>

Patent Storm. 2005. Application of biosensors for diagnosis and treatment of disease.

<http://www.patentstorm.us/patents/6974706-fulltext.html>

Sackner, MA. 2003. Selected Annotated Bibliography for the Lifeshirt™ System. VivoMetrics, Inc. http://www.vivometrics.com/docs/Vivo_2003_AnnotatedBibliography_Sackner.pdf

Rolan P, Atkinson AJ, Lesko LJ. 2003. Use of biomarkers from drug discovery through clinical practice: Report of the Ninth European Federation of Pharmaceutical Sciences Conference on Optimizing Drug Development. *Clinical Pharmacology & Therapeutics*. 73:284–291.

<http://www.nature.com/clpt/journal/v73/n4/full/clpt2003390a.htm>

U.S. Environmental Protection Agency (EPA). Human Health Research Program (HHRP). Biomarkers for Cumulative Risk. http://www.epa.gov/hhrp/quick_finder/biomarkers.html

Humane Endpoints

Humane Endpoints for Animals Used in Biomedical Research and Testing. *ILAR Journal* V41(2) 2000. http://dels.nas.edu/ilar_n/ilarjournal/41_2/ [accessed 22 January 2008].

OECD. 2000. Guidance Document on the Recognition, Assessment and Use of Clinical Signs as Humane Endpoints for Experimental Animals Used in Safety Evaluation. Environmental Health and Safety Monograph Series on Testing and Assessment No. 19. Paris, France: Organisation for Economic Co-operation and Development. Available: <http://www.oecd.org> [accessed 22 January 2008].

Regulatory Testing and Animal Welfare. *ILAR Journal* V43 Supplement 2002 . http://dels.nas.edu/ilar_n/ilarjournal/43_supp/ [accessed 22 January 2008].

Stokes WS. 2002. Humane Endpoints for Laboratory Animals Used in Regulatory Testing. *ILAR Journal* V43 Supplement. S31-S38. Available: http://dels.nas.edu/ilar_n/ilarjournal/43_supp/v43supStokes.pdf [accessed 22 January 2008].

Acute Toxicity Test Guidelines – Oral

EPA. 2000. Health Effects Test Guidelines OPPTS 870.3050. Repeated Dose 28–Day Oral Toxicity Study in Rodents. EPA 712–C–00–366. Washington, DC: U.S. Environmental Protection Agency. Available: http://www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/870_Health_Effects_Test_Guidelines/Series/870-3050.pdf [accessed 22 January 2008].

EPA. 2002a. Health Effects Test Guidelines OPPTS 870.1000 Acute Toxicity Testing – Background. EPA 712–C–02–189. Washington, DC: U.S. Environmental Protection Agency. Available: http://www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/870_Health_Effects_Test_Guidelines/Revised/870r-1000.pdf [accessed 22 January 2008].

EPA 2002b. Health Effects Test Guidelines OPPTS 870.1100 Acute Oral Toxicity. EPA 712–C–02–190. Washington, DC: U.S. Environmental Protection Agency. Available: http://www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/870_Health_Effects_Test_Guidelines/Revised/870r-1100.pdf [accessed 22 January 2008].

OECD. 1995. Guideline for Testing of Chemicals, 407: Repeated Dose 28-day Oral Toxicity Study in Rodents. Paris, France: Organisation for Economic Co-operation and Development. Available: <http://www.oecd.org> [accessed 22 January 2008].

OECD. 2001a. Guideline for Testing of Chemicals, 420, Acute Oral Toxicity – Fixed Dose

Method. Paris, France:Organisation for Economic Co-operation and Development. Available: <http://www.oecd.org> [accessed 22 January 2008].

OECD. 2001b. Guideline For Testing of Chemicals, 423, Acute Oral Toxicity – Acute Toxic Class Method. Paris, France:Organisation for Economic Co-operation and Development. Available: <http://www.oecd.org> [accessed 22 January 2008].

OECD. 2001c. Guideline for Testing of Chemicals, 425, Acute Oral Toxicity – Up-and-Down Procedure. Paris, France:Organisation for Economic Co-operation and Development. Available: <http://www.oecd.org> [accessed 22 January 2008].

OECD. 2001d. Guidance Document on Acute Oral Toxicity Testing. 24. Paris, France:Organisation for Economic Co-operation and Development. Available: <http://www.oecd.org> [accessed 22 January 2008].

Acute Toxicity Test Guidelines – Dermal

EPA. 1998a. Health Effects Test Guidelines OPPTS 870.1200 Acute Dermal Toxicity. EPA 712-C-98-192. Washington, DC: U.S. Environmental Protection Agency. Available: http://www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/870_Health_Effects_Test_Guide_lines/Drafts/870-1200.pdf [accessed 22 January 2008].

EPA. 1998c. Health Effects Test Guidelines OPPTS 870.3200 21/28-Day Dermal Toxicity. EPA 712-C-98-201. Washington, DC: U.S. Environmental Protection Agency. Available: http://www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/870_Health_Effects_Test_Guide_lines/Series/870-3200.pdf [accessed 22 January 2008].

OECD. 2004b. Guideline For Testing of Chemicals, TG 434: Acute Dermal Toxicity – Fixed Dose Procedure. Paris, France:Organisation for Economic Co-operation and Development. Available: <http://www.oecd.org> [accessed 22 January 2008].

Acute Toxicity Test Guidelines – Inhalation

EPA. 1998b. Health Effects Test Guidelines OPPTS 870-1300 Acute Inhalation Toxicity. EPA 712-C-98-193. Washington, DC: U.S. Environmental Protection Agency. Available: http://www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/870_Health_Effects_Test_Guide_lines/Series/870-1300.pdf [accessed 22 January 2008].

OECD. 2004a. Guideline For Testing of Chemicals, 433: Acute Inhalation Toxicity – Fixed Concentration Procedure. Paris, France:Organisation for Economic Co-operation and Development. Available: <http://www.oecd.org> [accessed 22 January 2008].

OECD. 2004c. Guideline For Testing of Chemicals, TG 436: Acute Inhalation Toxicity – Acute Toxic Class (ATC) Method. Paris, France:Organisation for Economic Co-operation and Development. Available: <http://www.oecd.org> [accessed 22 January 2008].

***In Vitro* Approaches**

ACuteTox: Research Project for Alternative Testing
An In-Vitro Test Strategy for Predicting Human Acute Toxicity. An Integrated Project within the Sixth Framework Programme.

<http://www.acutetox.org/index.php> [accessed 22 January 2008].

<http://www.acutetox.org/publications/index.php> [accessed 22 January 2008].

http://www.acutetox.org/docs/Publication/General_Publications/ACuteTox.Publishable_executive_summary2006.final.pdf [accessed 22 January 2008].

ICCVAM. 2001a. Report Of The International Workshop On *In Vitro* Methods For Assessing Acute Systemic Toxicity. NIH Publication No. 01-4499. Research Triangle Park, NC:National Institute for Environmental Health Sciences. Available: <http://iccvam.niehs.nih.gov/> [accessed 22 January 2008].

ICCVAM. 2001b. Guidance Document On Using *In Vitro* Data To Estimate *In Vivo* Starting Doses For Acute Toxicity. NIH Publication No. 01-4500. Research Triangle Park, NC:National Institute for Environmental Health Sciences. Available: <http://iccvam.niehs.nih.gov/> [accessed 22 January 2008].

***In Vitro* Methods for Acute Toxicity**

Gennari A, van den Berghe C, Casati S, Castell J, Clemedson C, Coecke S, et al. 2004. Strategies to replace *in vivo* acute systemic toxicity testing. The report and recommendations of ECVAM Workshop 50. *Altern Lab Anim* 32:437-459. <http://ecvam.jrc.it/> [accessed 22 January 2008].

ICCVAM. 2006a. ICCVAM Test Method Evaluation Report: *In Vitro* Cytotoxicity Test Methods for Estimating Starting Doses for Acute Oral Toxicity Tests. NIH Publication No. 07-4519. Research Triangle Park, NC:National Institute for Environmental Health Sciences. Available: http://iccvam.niehs.nih.gov/methods/acutetox/inv_nru_tmer.htm [accessed 22 January 2008].

ICCVAM. 2006b. Peer Panel Report: The Use of *In Vitro* Basal Cytotoxicity Test Methods for Estimating Starting Doses for Acute Oral Systemic Toxicity Testing. Research Triangle Park, NC:National Institute for Environmental Health Sciences. Available: http://iccvam.niehs.nih.gov/methods/acutetox/inv_nru_scpeerrev.htm [accessed 22 January 2008].

Alternative Test Methods

ICCVAM. 2001. The Revised Up-and-Down Procedure (UDP): A Test Method for Determining the Acute Oral Toxicity of Chemicals (Volumes 1 and 2). NIH Publication No. 02-4501 - November 2001. Research Triangle Park, NC:National Institute for Environmental Health Sciences. Available: http://iccvam.niehs.nih.gov/methods/acutetox/udp_report.htm [accessed 22 January 2008].

ICCVAM. 2007. Draft NICEATM-ICCVAM Five-Year Plan. Research Triangle Park, NC:National Institute for Environmental Health Sciences. Available: <http://iccvam.niehs.nih.gov/docs/5yearplan.htm> [accessed 22 January 2008].

General References

Committee on Toxicity Testing and Assessment of Environmental Agents, National Research Council. 2007. Toxicity Testing in the Twenty-first Century: A Vision and a Strategy. Washington, DC: National Academies Press. Available: <http://books.nap.edu/catalog/11970.html> [accessed 22 January 2008].

EPA. 2007. EPA Categorization and Prioritization Community of Practice. Available: http://www.epa.gov/ncct/practice_community/category_priority.html [accessed 22 January 2008].

NTP. 2004a. Toxicology in the 21st century: The role of the National Toxicology Program. Research Triangle Park, NC: National Institute for Environmental Health Sciences. Available: http://ntp-server.niehs.nih.gov/ntp/main_pages/NTPVision.pdf [accessed 22 January 2008].

NTP. 2004b. A National Toxicology Program for the 21st Century: A Roadmap for the Future. <http://ntp.niehs.nih.gov/files/NTPrdmp.pdf> [accessed 22 January 2008].

Solecki R, Davies L, Dellarco V, Dewhurst I, van Raaij M, Tritscher A. 2005. Guidance on setting of acute reference dose (ARfD) for pesticides. Food Chem Toxicol 43:1569–1593.