

Endocrine Disruptor Screening Services



RTI offers *in vitro* and *in vivo* toxicology testing to the agricultural, pharmaceutical, and commodity chemical industries for both EPA-mandated assays and European Union REACH (Registration, Evaluation, Authorisations and Restriction of Chemicals) initiatives.

Compelling evidence of adverse effects of chemical contaminants on the endocrine systems of certain fish and wildlife led Congress to require the U.S. Environmental Protection Agency (EPA) to initiate the Endocrine Disruptor Screening Program (EDSP) to evaluate pesticide chemicals and other environmental contaminants for their potential to affect the endocrine systems of humans and wildlife.

In October 2009, EPA began publishing test orders for the first 67 chemicals to come under the EDSP Tier 1 testing requirement, with a data submission deadline of two years.

As one of the main laboratories chosen to provide assay pre-validation and validation services to EDSP, RTI has eight years of experience conducting many of the Tier 1 assays in compliance with what is now the EDSP testing requirement.

Experienced Scientific Leadership and Study Directors

RTI has amassed more than 35 years of experience conducting GLP-compliant developmental and reproductive toxicity (DART) studies, including endocrine toxicology studies. Current GLP-compliant studies are conducted under the guidance of Dr. Rochelle Tyl, DABT, Senior Director of our DART Program, RTI Distinguished Fellow, and a former President of the Teratology Society.

Under her leadership, DART study directors—who each have from 16 to 30 years of experience conducting GLP-compliant studies—bring the benefits of our knowledge and familiarity to bear on behalf of our clients.

The RTI team has eight years of experience conducting and directing validation studies for the EDSP contracts issued by EPA (see reference list and www.epa.gov/endo for validation reports).

Capabilities

RTI conducts the following assays required for EDSP Tier 1 screening:

In Vivo Assays

- Uterotrophic (rat, ovariectomized adult and intact weanling)
- Hershberger (rat)
- Pubertal female (rat)
- Pubertal male (rat)

In Vitro Assays

- Estrogen receptor (ER) binding—rat uterine cytosol
- Estrogen receptor—(hER α) transcriptional activation—Human cell line (HeLa-9903)
- Androgen receptor (AR) binding—rat prostate cytosol
- Steroidogenesis—Human cell line (H295R)
- Aromatase—Human recombinant microsomes

Endocrine Disruptor Screening Services

We also conduct the adult male assay, hormone challenge assays, and other assays used to detect endocrine effects. Our scientists are skilled at including the evaluation of endocrine effects in other study designs.

Selected RTI Publications on Endocrine Disruptors

Tyl, R.W.; Marr, M.C.; Brown, S.S.; Dolbrow, E.A.; Myers, C.B. Validation of the Intact Rat Weanling Uterotrophic Assay with Notes on the Formulation and Analysis of the Positive Control Chemical in Vehicle. *J. Appl. Toxicology*, in press.

Tyl, R.W.; Myers, C.B.; Marr, M.C.; Sloan, C.S.; Castillo, N.P.; et al. Two-Generation Reproductive Toxicity Evaluation of Dietary 17 β -Estradiol (E2; CAS No. 50-28-2) in CD-1 (Swiss) Mice. *Toxicol. Sci.* **2008**, *102*: 392-412.

Tyl, R.W.; Sloan, C.S.; Hamby, B.T.; Ehman, K.D.; Sumner, S.J. Background Review Document on the Rodent Hershberger Bioassay. **2006**. EDSP, EPA: Washington, DC. Available from <http://www.oecd.org/dataoecd/18/57/37880949.pdf>.

Brueggemeier, R.W.; Sloan, C.S.; Mathews, J.M.; Black, S.L. Final Detailed Review Paper On Aromatase. **2005**. EDSP, EPA: Washington, DC. Available from http://www.epa.gov/endo/pubs/edmvs/aromatase_drp_final_3_30_05.pdf.

Fail, P.A.; Sloan, C.S.; Johnson, J.D.; Brown, V.J. Detailed Review Paper on Steroidogenesis Screening Assays and Endocrine Disruptors. **2005**. EDSP, EPA: Washington, DC. Available from http://www.epa.gov/endo/pubs/edmvs/steroidogenesis_drp_final_3_29_05.pdf.

Sloan, C.S.; Pearce, S.W. Hormone Concentration Determination in Rat Serum Samples for GLP Study, Inter-Laboratory Validation of the 15-Day Intact Male Rat Assay. **2005**. Commercial client.

Sloan, C.S.; Pearce, S.W.; Myers, C.B.; Tyl, R.W.; George, J.D.; Marr, M.C.; Hamby, B.T. Inter-Laboratory Validation of the 15-Day Adult Intact Male Rat Assay with Linuron and Phenobarbital: Final Report. **2005**. EDSP, EPA: Washington, DC. Available from http://www.epa.gov/endo/pubs/interlab_rti_final.pdf.

Sloan, C.S.; Tyl, R.W.; George, J.D.; Goodman, A.B.; Pearce, S.W. Sliced Testis Assay Prevalidation: Multichemical Study:

Final Report. **2004**. EDSP, EPA: Washington, DC. Available from http://www.epa.gov/scipoly/oscpendo/pubs/edmvs/slicedtestismultichemicalprevalidation_11_17_04.pdf.

Sloan, C.S.; Vick, K.D.; Fail, P.A. Hershberger Assay Standardization and Validation Studies: Methyltestosterone Dose Range Finding Study, Dose Response Curve and Flutamide Response: Phase 1, Experiment A and B. **2004**. Commercial client.

Sloan, C.S.; Vick, K.D.; Fail, P.A. Hershberger Assay Standardization and Validation Studies: Testosterone Propionate Dose Response Curve-Phase 1, Experiment A. **2003**. Commercial client.

Parker, S.P.; Tyl, R.W. White Paper on Species/Strain/Stock in Endocrine Disruptor Assays. **2003**. EDSP, EPA: Washington, DC. Available from <http://www.epa.gov/scipoly/oscpendo/pubs/edmvs/strainswhitepaper072503.pdf>.

George, J.D.; Tyl, R.W.; Hamby, B.T.; Myers, C.B.; Marr, M.C. Assessment of Pubertal Development and Thyroid Function in Juvenile Female CD (Sprague-Dawley) Rats After Exposure to Selected Chemicals Administered by Gavage on Postnatal Days 22 to 42/43: Final Report. **2003**. EDSP, EPA: Washington, DC. Available from <http://www.epa.gov/scipoly/oscpendo/docs/edmvs/femalepubertalshortreportnov1103.pdf>.

George, J.D.; Tyl, R.W.; Hamby, B.T.; Myers, C.B.; Marr, M.C. Assessment of Pubertal Development and Thyroid Function in Juvenile Male CD (Sprague-Dawley) Rats After Exposure to Selected Chemicals Administered by Gavage on Postnatal Days 23 to 52/53: Final Report. **2003**. EDSP, EPA: Washington, DC. Available from <http://www.epa.gov/scipoly/oscpendo/docs/edmvs/malepubertalshortreportnov1103.pdf>.

More Information

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