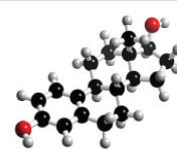


Gradient



NEWS ALERT

US EPA's Endocrine Disruptor Screening Program Update

On October 21, 2009, the US Environmental Protection Agency (US EPA) announced the official beginning of its Endocrine Disruptor Screening Program (EDSP), which was first envisioned in 1996. US EPA will start issuing Tier 1 screening orders for the first group of 67 chemicals (59 pesticide active ingredients and 9 chemicals used as pesticide inert ingredients) between October 2009 and February 2010. The kick-off to this massive chemical screening program was accompanied by two notices on the *Federal Register*:

- Tier 1 Screening Orders for the EDSP ([EPA-HQ-OPP-2009-0634](#)); and
- Tier 1 Screening Battery and Related Test Guidelines for the EDSP ([EPA-HQ-OPPT-2008-0521](#));

Order recipients have 90 days to respond, and the Tier 1 screening data required to satisfy an order are due within two years of the date of issuance of the order. The screening phase requires data ideally obtained from all of US EPA's proposed 11 screening assays, with total costs expected to be close to \$1,000,000 per chemical. However, order recipients have the option to submit "*other scientifically relevant information*" (OSRI) in lieu of the ordered screening assays within 90 days of the order issuance date. Note that anyone (*i.e.*, persons other than order recipients) has the option of submitting OSRI on any of the chemicals targeted for Tier 1 screening within the same 90-day time period.

Several unresolved technical issues remain at the start of the EDSP:

- Continued concerns with the validation of the Tier 1 assay battery;
- Uncertainty regarding the finality of the Tier 1 assay battery (*i.e.*, US EPA is continuing to develop the Tier 1 screening battery as the state of the science advances and might consider additional assays in the future);
- Lack of clear US EPA guidance on how results will be interpreted and on what basis chemicals will be retained for Tier 2 testing;
- Potential lack of capacity and/or capability by contract labs to run the proposed assays; and
- Potential lack of capacity at US EPA to evaluate OSRI submitted by order recipients and others in a timely manner.

Gradient's experts have been closely involved in research and priority-setting for the regulatory screening and testing of endocrine disruptors. [Dr. Lorenz Rhomberg](#), a leading expert in the interpretation of toxicological data using weight-of-evidence approaches, has been actively addressing scientific issues associated with endocrine disruption for more than 10 years. In 1997, he published a study titled, "Beyond screening: Problems and prospects for risk characterization of endocrine disruptors" (*Regulatory Toxicology and Pharmacology* 26:74-79). [Dr. Tim Verslycke](#), an environmental toxicologist, has been involved in basic and applied research (*e.g.*,

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Upcoming Gradient Events / Presentations:

[J. Goodman](#), [T. Verslycke](#), C. Mori, and [L. Rhomberg](#). "New developments in exploratory research on "estrogenicity" – Progress toward validation of new end points and testing methods" at the Society of the Plastics Industry's Meeting, December 3, 2009, Atlanta, GA

[L. Rhomberg](#) and [T. Verslycke](#). "EDSP Scientific and Regulatory Compliance." Gradient-hosted breakfast seminar, January 2010, Washington, DC.

Tier-2 mysid shrimp and Tier-1 ER binding assay development) on endocrine disruptors and pharmaceutical and personal care product ingredients for 10 years.

Gradient can assist you with:

- Selecting contract laboratories;
- Design and oversight of appropriate screening;
- Identifying and compiling "other scientifically relevant information";
- Interpretation of screening results using state-of-the-science weight-of-evidence approaches;
- Agency interactions; and
- Communication strategies.

