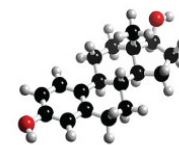


# Gradient



## NEWS ALERT

### US EPA's Endocrine Disruptor Screening Scope Broadens

On November 17, 2010, The US Environmental Protection Agency (US EPA) published a second list of 134 chemicals for Tier 1 Screening under the Endocrine Disruptor Screening Program ([docket: EPA-HQ-OPPT-2009-0477](#)). This second list broadens the scope of chemicals from 67 pesticide active and inert ingredients to include pharmaceutical and personal care product ingredients, common solvents, and a range of other industrial chemicals. Consequently, the EDSP will now affect a much wider range of chemical manufacturers, importers, and processors. US EPA identified close to 1,000 test order recipients for the second list. Given that the key driver for this second list was an Appropriations Committee Report ([H.R. 2996, H. Rept. 111-180](#)), many order recipients may not have had the time to adequately prepare for this massive screening program. To inform the exclusion or inclusion of chemicals on the second EDSP list, comments must be submitted to the agency by **December 17, 2010**.

The announcement of this second EDSP list was accompanied by two other notices in the *Federal Register*:

- Draft Policies and Procedures for Screening Safe Drinking Water Act Chemicals ([docket EPA-HQ-OPPT-2007-1081](#)) – Comments due **January 18, 2011**
- A Draft Weight-of-Evidence Guidance Document: Evaluating Results of EDSP Tier 1 Screening to Identify Candidate Chemicals for Tier 2 testing ([docket: EPA-HQ-OPPT-2010-0877](#)) – Comments due **January 3, 2011**

Recipients of the second round of EDSP orders have 90 days to respond (150 days for consortia), and the Tier 1 screening data required to satisfy an order are due within 2 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. While order recipients have the option to submit 'other scientifically relevant information' (OSRI) in lieu of the ordered screening assays, experience with the first list indicates very low agency acceptance of OSRI (as of October 28, EPA has denied 26 of 29 OSRI petitions).

Several unresolved issues remain at the start of the second EDSP list:

- Continued concerns with the validation of the Tier 1 assay battery;
- US EPA's Draft Weight-of-Evidence Guidance document provides little clarity on how results will be interpreted and on what basis chemicals will be retained for Tier 2 testing. It is also unclear how Tier 2 results will be weighted to make final regulatory decisions;

### For more information on Gradient's work with Endocrine Disruptors, contact:

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### Recent Gradient Presentation:

Erik Janus, Tim Verslycke, and Wendelyn Jones. "Setting the Stage for Successful Chemical Policy Implementation: The EDSP Policy Microcosm." at the Society of Environmental Toxicology and Chemistry (SETAC) North America Meeting, November 7-11, 2010, Portland, OR. For a copy of the poster, contact Tim Verslycke.

Gradient is an environmental and risk science consulting firm renowned for our specialties in Toxicology, Epidemiology, Risk Assessment, Product Safety, Contaminant Fate and Transport, and Environmental Chemistry. We employ sound science to assist national and global clients in resolving their complex problems relating to chemicals in the environment, in the workplace, and in consumer products.

- Several other legislative initiatives and regulatory programs will address putative endocrine disruptive chemicals and it is unclear whether data gathered under the EDSP will be sufficient to satisfy future screening and testing requirements.

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., 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 specifically 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.

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