

# Gradient Corporation



## NEWS ALERT

### US EPA's Endocrine Disruptor Screening Program Update

The United States Environmental Protection Agency (US EPA) announced on April 29th that it could issue its first batch of Tier 1 test orders to pesticide manufacturers, registrants, and importers under its Endocrine Disruptor Screening Program (EDSP) by July 2009. These upcoming orders mark the beginning of a massive chemical screening program first envisioned in 1996. On April 15th, US EPA published three notices in the *Federal Register*:

- A list of initial pesticide active and inert ingredients to be screened under the federal Food, Drug, and Cosmetic Act ([docket: EPA-HQ-OPPT-2004-0109](#));
- An announcement of the revised policies and procedures for the EDSP ([docket: EPA-HQ-OPPT-2007-1080](#)); and
- A request for public comments on the Information Collection Request ([docket: EPA-HQ-OPPT-2007-1081](#)).

US EPA estimates that as many as 390 Tier 1 test orders may be sent. Although the testing schedule is subject to final public comments and White House review, it now seems very likely that testing will start later this year, despite many unresolved technical issues, such as:

- Lack of a fully validated Tier 1 assay battery;
- Lack of clear US EPA guidance on how results will be weighted and on what basis chemicals will be retained for Tier 2 testing; and
- Lack of capacity and capability by contract labs to run the proposed assays.

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 test laboratories;
- Design and oversight of appropriate testing;
- Interpretation of test results using state-of-the-science weight-of-evidence approaches;
- Public comment and agency discussions; and
- Communication strategies.

For more information on Gradient's work with [Endocrine Disruptors](#), contact:

[Tim Verslycke](#),  
Ph.D.  
Senior Environmental Toxicologist  
[tverslycke@gradientcorp.com](mailto:tverslycke@gradientcorp.com)

Gradient will keep you informed of developments in the EDSP. We are **planning a breakfast seminar in the Washington, DC, area in late summer 2009** to discuss the EDSP scientific and regulatory compliance issues (a hold-the-date request will be emailed to you soon).



Gradient Corporation  
20 University Road  
Cambridge, MA 02138  
Phone: 617-395-5000  
[www.gradientcorp.com](http://www.gradientcorp.com)

**Gradient**  
CORPORATION