



EDSP STATUS AND REVIEW PLAN FOR INERTS

EPA/CPDA Symposium on Inert Ingredients

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TIER I ASSAYS**COST ESTIMATES**

	low	typical	high
<hr/> <i>In Vitro Assays:</i> <hr/>			
Androgen Receptor Binding (Rat Prostate)	\$10,000		\$20,000
Aromatase (Human Recombinant)	\$10,000		\$20,000
Estrogen Receptor Binding (Rat Uterine)	\$10,000		\$20,000
Steroidogenesis (Human Cell Line)	\$10,000		\$20,000
<hr/> <i>In Vivo Assays:</i> <hr/>			
Fish Short Term Reproduction	\$99,000	\$110,000	\$150,000
Hershberger (Rat)	\$60,000	\$71,000	\$84,000
Female Pubertal (Rat)	\$115,000	\$145,000	\$190,000
Male Pubertal (Rat)	\$120,000	\$155,000	\$200,000
Amphibian Metamorphosis (Frog)	\$90,000	\$98,000	\$120,000
Uterotrophic (Rat)	\$55,000	\$65,000	\$76,000
ER Transcriptional Activation	\$10,000		\$15,000
<hr/> <i>Analytical Chemistry methods for dose confirmation (cost per assay)</i> <hr/>			
	\$10,000	\$12,000	\$20,000
TOTALS	\$699,000		\$1,135,000

Estimated Tier I Burden

	Cost Estimates	
	low	high
Cost of Tier I Battery	\$699,000	\$1,135,000
Battery plus Consortium Costs	\$943,650	\$1,532,250
Total Cost of 67 Tier I Batteries	\$63,224,550	\$102,660,750

Status of Industry Activity and Concerns

- Some in initial 90-day response period, some into 150-day consortium response period
- Some chemicals may be tested by more than one company and/or consortium, some by none
- Some registration cancellations already
- Testing of inerts is uncertain
- “May” versus “may not” interaction determination process unclear
- Cost and implications of Tier 2 testing are unknown; this affects decision to conduct Tier 1 testing

EDSP Information Collection Request

OMB Action: Approved with Change

“Terms of Clearance”

- “...under the principles of the PRA, EPA should promote and encourage test order recipients to submit Other Scientifically Relevant Information (OSRI) in lieu of performing all or some of the Tier I assays, and **EPA should accept OSRI as sufficient to satisfy the test orders to the greatest extent possible.**”
- “...to further validate EPA’s burden estimates, OMB requests that EPA provide a report re-estimating the burden of this information collection based on responses to the Tier I test orders, including the use of cost-sharing and data compensation, the **submission and acceptance of existing data and OSRI, and description of any instances in which submission of OSRI was deemed insufficient to satisfy the testing order.**”
- “... in order to ensure that EPA has maximized the practical utility of the Tier I assays..., EPA should ensure sufficient opportunity prior to submission of any revision to this collection for **public comment and peer review of the EPA tools to be developed** to guide the agency decisions on whether a chemical must proceed to Tier II, including the Weight of Evidence Approach and Standard Evaluation Procedures.”

Issues and Concerns:

- Existing Data and Other Scientifically Relevant Data
 - How will EPA evaluate this? When will industry know the results?
- Practical Utility (Benefit) of the Collection
 - Does the Battery provide the needed result to justify the data collection? Is existing data sufficient?
- Burden (Cost) of the Collection
 - Few labs conducting new tests with poor reference chemicals



Thank you!