

Poster: ecotoxicology – endocrine disruptors

Application of an intelligent testing strategy to the US EPA Endocrine Disruptor Screening Program

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The US EPA is initiating its Endocrine Disruptor Screening Program in the fall of 2008. The EPA has designed its program in two tiers. The purpose of the Tier 1 is to “identify substances that have the potential to interact with the EAT [estrogen/androgen/thyroid] hormonal systems...”, and the results would then be used to trigger Tier 2 testing (reproductive and developmental toxicity studies). At the time the Tier 1 battery was available for public comment (FIFRA Scientific Advisory Panel Meeting, March 25-26, 2008), it tentatively consisted of three to four *in vitro* methods, five *in vivo* methods, and four alternate methods (one *in vitro*, three *in vivo*). For the initial phase of the EDSP, every chemical that receives a Data Call-In notice from the EPA must be tested in all of the assays that will eventually comprise the Tier 1 battery. Although the specifics of the Tier 1 battery are still in flux, it appears likely to consist of approximately 10 assays that would use from 475 to more than 1,100 animals and cost between 220,000 to more than 700,000, USD per chemical (conservatively estimated with no range-finding or repeat experiments). Since not all of the methods – or the assumed battery – have been thoroughly validated, it is likely that the Tier 1 will be revised. Recognising the need for a faster, more accurate, valid screening battery, we propose an alternative tiered strategy here. The preliminary tier includes physical and chemical data, existing toxicological data, and *in vitro* and (Q)SAR methods that are either validated or nearly validated. The results of this alternative Tier 1 can be used in a weight-of-evidence approach to 1) identify priority chemicals and 2) design an intelligent, chemical-specific strategy for further screening or testing. Such a strategy would greatly reduce the use of animal testing for identification and classification of endocrine disrupting chemicals.

References

1. According to the presentation given by the EPA on March 25th, 2008 at the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel Meeting, the In utero through lactation assay is still being considered as an alternate assay, even though at a FIFRA on February 21, 2007 meeting to discuss the test was criticized as being too expensive for a Tier 1 test.
2. EDSTAC Final Report, January 2004, Table 5.6. <http://www.epa.gov/endo/pubs/edstac/chap5v14tbl.pdf>.
3. The in utero-through lactation assay itself is estimated to cost approximately 300,000 USD

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