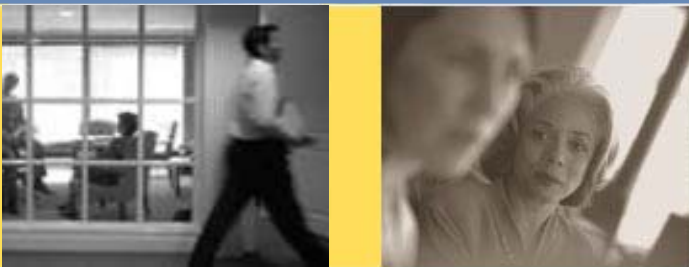


EPA's Endocrine Disruptor Screening Program: The Pesticide Industry Experience

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Objectives:

- Review the history of pesticide industry involvement in the development of the EDSP
- Review how the pesticide industry self-organized in preparation of first EDSP test orders
- Describe experiences with the program to-date and comment on how to improve the path forward

A brief history of the EDSP

- Early- to mid-90s: provocative (and often poorly researched) publications such as Our Stolen Future raise some new concerns ...



“A large number of man-made chemicals that have been released into the environment, as well as a few natural ones, have the potential to disrupt the endocrine system of animals, including humans. Among these are the persistent, bioaccumulative, organohalogen compounds that include some pesticides (fungicides, herbicides, and insecticides) and industrial chemicals, other synthetic products, and some metals.”

A brief history of the EDSP

- The first shoe drops: FQPA (1996) & SDWA amendments result from increased attention to EDCs by both the public and Congress
 - EPA's duty under FQPA: “... *develop a screening program using **appropriate validated test systems** and **other scientifically relevant information**, to determine whether certain substances **may have an effect in humans** that is similar to an effect produced by a naturally occurring estrogen **or any other such endocrine effect as the Administrator may designate.**”*

A brief history of the EDSP

- Throughout the 90s and into the 2000s: EDSTAC* and EDMVAC* get to work
- EDSTAC: comprised over 30 members from gov't, academia, industry, NGOs
 - Provided technical recommendations for how to screen and what to screen
 - Established framework and process for prioritizing and testing chemicals through a tiered system (“screening” and “testing”)

* ED Screening & Testing Advisory Committee; ED Methods Validation Advisory Committee

A brief history of the EDSP

- EDMVAC: convened to coordinate and implement the EDSTAC suggestions, including conducting the work necessary to validate the tests recommended by EDSTAC
 - Ran as a FACA during 2005-2006
 - Terminated by EPA in December 2006
- EPA has since then worked independently with contract labs to complete validation of the screening battery

A brief history of the EDSP

- The other shoe drops: 2000 EPA EDSP Report to Congress
 - Agency adopted phase-in approach to screening, including the notion that a priority list of pesticides (with extensive tox databases!) should undergo screening and this priority screening would essentially constitute a secondary validation
 - Direct conflict with EDSTAC, which did not recommend routine testing of pesticides with extensive databases
 - TRUE purpose of T1 screen: “determine the potential for interaction with the endocrine system”

A brief history of the EDSP

- Final SAP “endorsement” of Tier 1 battery given to EPA in March 2008
- Final List of pesticide active/inerts; Revised Policies & Procedures; Request for Comments on the Information Collection Request all released in April 2009
- 2 October 2009: OMB OIRA approves EPA ICR
- 29 October 2009: First EDSP Tier 1 Test Orders went out to registrants

How did the industry respond?

- Submitted petition to EPA
- Held meetings with EPA OPPTS staff
- Held meetings with OMB OIRA staff
- Submitted multiple rounds of comments
- Established the Endocrine Policy Forum to “speak with one voice” in response to EDSP Test Orders

Pesticide industry response to EDSP

- “Petition for a Scientifically Sound and Legally Valid EDSP” submitted to Admin. Johnson in July 2008 (subsequently denied in April 2009) by CropLife America
- CLA suggested EPA should:
 - ❑ Review existing data on a case-by-case basis prior to issuing Test Orders
 - ❑ Fully validate individual T1 assays as well as full battery
 - ❑ Develop SOPs for evaluating, interpreting and applying T1 data
 - ❑ Finalize process by which T1 data trigger T2 testing
 - ❑ Prepare appropriate impact analyses (PRA, SBREFA)

Pesticide industry response to EDSP

- During meetings with both OPPTS (now OCSP) and OMB OIRA staff, CLA and allies pushed for:
 - ❑ Use of existing FIFRA data to satisfy the needs of the T1 screening in a “functionally equivalent” manner
 - ❑ Full international validation of all tests/batteries
 - ❑ Implementing EDSP in a phased approach, starting only with fully validated tests and proceeding with others as additional work is done
 - ❑ Replacing the male/female pubertal assays with the 15-day intact male assay

Pesticide industry response to EDSP

- CLA submitted multiple rounds of comments (as did allies) ... some solicited, some not:
 - ❑ Public oral/written comments given at 2008 SAP meeting
 - ❑ Several rounds of written comments went in during early 2008 (list, policies, battery)
 - ❑ Detailed comments on the final OPPTS TGs were submitted unsolicited earlier this year
 - ❑ Additional unsolicited comments planned for later this year (SOPs, T2 triggering criteria)

CropLife America “Endocrine Policy Forum”

- Officially established 1 January 2010 to engage EPA with “one voice” on behalf of the pesticide industry
- Composed of over 20 pesticide registrants, including some non-CLA members and trade associations
- Split into technical & policy working groups
- Managed by external Scientific Coordinators
- Expected to last at least 3 years (during lifespan of the current EDSP ICR, set to expire by October 2012)

Industry experiences with EDSP implementation to date

- “A day late and a dollar short ...”
- Refusal to discuss technical aspects of program since issuance of Test Orders
- Major delays expected with first round of OSRI reviews/Test Order response review
- Tier 1 testing battery still has validation issues as well as “overly prescriptive” TGs that may impact study repeat/rejection rate
- More deference given to Congress than EOP/OMB
- No guidance yet on data acceptability, evaluation, interpretation, application ...

What does the landscape of the path forward look like?

- Test Order responses due back last week!
 - What will be the result of EPA review of OSRI data?
What will the industry response be?
- Tier 2 battery validation is ongoing.
 - How will T1 trigger T2? Why can't companies go straight to T2?
- OPPTS TGs need to be publically peer reviewed!
 - Last SAP review was in 2008 and they have changed significantly
- EPA desperately needs SOPs and WOE strategies for data processing

What does the landscape of the path forward look like?

- Interpretation of T1 data???
 - How will EPA do this? How will they train their staff for consistent application of criteria and/or SOPs?
- Use of “21st Century tools”???
 - How will EPA demonstrate “proof of concept” for greater use of *in vitro*, *in silico* data streams?
- 2nd list of EDSP chemicals to contend with.
 - EPA appears to be addressing the desires of Congress over the requirements laid out by OMB in the EDSP ICR.

Other complicating factors ...

- Endocrine has returned to the Hill!
 - Reps. Slaughter (D-NY), Markey (D-MA) have introduced bills, as has Sen. Kerry (D-MA)
 - Bills seek to fold in NIEHS into the EDSP process – this is poorly timed and detrimental to the process.
- Long term communication issues exist.
 - How will EPA “advertise” chemicals that get a clean bill of health through EDSP?

Some concluding thoughts

- Lack of leadership and resources over time has resulted in a less than ideal situation for both the industry and EPA
- Unclear how existing pesticide data will be considered; outcome also unclear
- Lack of attention to standardized approaches is problematic
- Political considerations are poised to trump scientific ones once again!

Thanks for your time and attention!

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