

US EPA ARCHIVE DOCUMENT



# Overview of the EPA's Endocrine Disruptor Screening Program

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May 12, 2005

# EPA's Legislative Mandates (August 1996)

- **Food Quality Protection Act, Sec. 408(p)**
  - Must screen pesticides for estrogenic effects that may affect human health
  - Must use appropriate validated test systems or other scientifically relevant information
  - Can include other endocrine effects
- **Safe Drinking Water Act, Sec. 136**
  - Can screen drinking water contaminants to which substantial numbers of persons are exposed

# Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC)

- Chartered Oct 16, 1996 ([www.epa.gov/scipoly/oscpendo](http://www.epa.gov/scipoly/oscpendo))
- 39 members representing broad constituencies
- Recommendations proposed in 1998:
  - Estrogen, androgen and thyroid
  - Human and ecological effects
  - Broad universe of chemicals
  - Tier 1
    - *In vitro* and *in vivo* screens
    - Detect potential to interact with endocrine system
  - Tier 2
    - Multi-generation studies covering a broad range of taxa
    - Provide data for hazard assessment

# EPA's EDMVAC under FACA

- ED Methods Validation Advisory Committee (EDMVAC) under FACA - Chartered in May 2004
  - Scientific experts (in vitro, in vivo, multiple taxa)
  - Representing Industry, environmental groups, animal welfare, states, federal agencies, academia...
  - Purpose: to provide input and advice on the assays throughout validation process
- First Public meeting of the 20 members was held April 26 - 28, 2005

# Endocrine Disruptor (ED) Activities



- ED Screening . . . . . (EDSP)
  - Development and validation of the Tier 1 and Tier 2 assays, EDMVAC
  - Approaches for selecting the chemicals to be screened for ED
  - Regulatory implementation procedures for requiring ED testing

# Work Accomplished: Tier 1 Assays

<i>In vitro</i>	Method Development	Pre-validation Studies	Inter-lab Val Studies
ER (rat cytosol)	●	●	○
hrER binding <sup>OECD, a</sup>	●	○	
AR (rat cytosol)	●	●	○
hrAR binding <sup>OECD, a</sup>	●		
Steroidogenesis - rat sliced testes	●	○	
- H295R <sup>OECD, a</sup>	●	○	
Aromatase - placenta	●	●	○
- recombinant <sup>a</sup>	●	●	○

<sup>a</sup> alternate    ○ in progress    ● completed

# Work Accomplished: Tier 1 Assays

<i>In vivo</i>	Method Development	Pre-validation Studies	Inter-lab Val Studies
Hershberger <sup>OECD</sup>	●	●	○
Uterotrophic <sup>OECD</sup>	●	●	●
Pubertal (female)	●	●	○
Pubertal (male)	●	●	○
Frog metamorphosis OECD	●	○	
Fish screen <sup>OECD</sup>	●	○	

○ In progress    ● Completed

## Work Accomplished: Tier 2 Assays

	Method Development	Pre-validation	Validation
Mammalian 2-gen*		○	
Avian 2-gen*	●	○	
Amphibian dev, repro*	●	○	
Mysid 2-gen	●	○	
Fish 2-gen*	●	○	
<i>In utero/lactation</i>	●	○	

\* OECD

○ In progress

● Completed

## Chemical Selection and Priority Setting

- December 30, 2002 notice proposed a measure-based approach for selecting first 50 -100 chemicals to be subject to the new rule.
  - Pesticide chemicals to be selected based on
    - High production volume
    - Presence in food
    - Presence in drinking water
    - Occupational contact
  - HPV/Inerts to be selected based on
    - High production volume
    - Monitoring data that shows presence in human tissue, fish tissue, drinking water or indoor air

# EDSP Timeline

2000    2001    2002    2003    2004    2005    2006    2007    2008

