

US EPA ARCHIVE DOCUMENT

U.S. EPA EDSP Overview and Update

Pesticide Program Dialogue Committee
November 8-9, 2006

EPA's Statutory Authority

■ Food Quality Protection Act (FQPA)

Requires EPA to: Develop a screening program using validated assays to identify pesticides that may have estrogenic effects in humans.

Authorizes EPA to include:

Other endocrine effects, as designated by the EPA Administrator (e.g., androgen and thyroid; endocrine effects in species other than humans).

Other non-pesticide chemicals that:

- Have “an effect cumulative to that of a pesticide,” and
- To which a substantial human population may be exposed.

■ Safe Drinking Water Act (SDWA) Amendments

Allow EPA to require testing of chemical substances found in sources of drinking water, if a substantial human population may be exposed.

Endocrine Disruptor Screening Program (EDSP)

Established in 1999 following recommendations of:

- the Federal Advisory Committee Act (FACA) chartered Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) of 1996-1998;
- public comment; and
- EPA's Science Advisory Board & FIFRA Scientific Advisory Panel

Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC)

- Chartered Oct. 16, 1996
(www.epa.gov/scipoly/oscpendo)
- 39 members representing broad constituencies
- Recommendations proposed in 1998:
 - Estrogen, androgen and thyroid
 - Human and ecological effects
 - Priority setting for broad universe of chemicals
 - 2-Tiered Approach

Two-Tiered Approach

- 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

Current EDSP Activities



- **Assay Validation** - Development and validation of test assays (Tier 1 screening & Tier 2 testing)
- Priority Setting - Selecting chemicals to be screened
- Procedures - Developing implementation procedures for requiring testing

Validation Process for EDSP

- Method development and preparation of Detailed Review Paper (DRP)
- Pre-validation
 - Demonstration of relevance
 - Development of standard optimized protocol
 - Determination of readiness for validation
- Validation in multiple laboratories
 - Demonstrate reliability across labs
- Independent scientific peer review of validation effort
- Regulatory acceptance

Validation Update on Tier 1 Assays

■ Uterotrophic	Complete
■ Hershberger	2007-Q1
■ Adult Male	2007-Q1
■ Amphibian Metamorphosis	2007-Q2
■ Fish Screen	2007-Q3
■ Aromatase	2007-Q3
■ Female Pubertal	2007-Q3
■ Male Pubertal	2007-Q3
■ Battery	2007-Q4
■ ER/AR Binding	2008-Q1
■ Steroidogenesis	2008-Q2

Validation Update on Tier 2 Assays

- Mammalian 2-generation – Complete
- Avian 2-generation – 09/10
- Amphibian Growth/Reproduction – 09/10
- Fish 2-generation – 09/10
- Mysid 2-generation – 09/10

Current EDSP Activities



- Assay Validation - Development and validation of test assays (Tier 1 screening & Tier 2 testing)
- **Priority Setting** - Selecting chemicals to be screened
- Procedures - Developing implementation procedures for requiring testing

Priority Setting

Selection of Initial List of 50-100 Chemicals for Screening

- Selection to be based on potential human exposure
- Pesticide actives and HPVs / pesticide inerts
 - 4 pathways for PAIs (food, water, residential, occupational)*
 - 4 pathways for HPV inerts (human and eco biomonitoring, water, air)*
- Higher priority for chemicals found in multiple pathways, and for PAIs in food and HPV/inerts in human biomonitoring data

Data Analysis

- Pesticide Active Ingredients
 - *approximately 1,100 total*
 - *>600 on one or more pathway lists*
 - *~100 on 3 or 4 pathway lists*
- High Production Volume Inerts
 - *approximately 650 HPV / Pesticide Inerts*
 - *<100 on one or more pathway lists*
 - *~15 on 3 or 4 pathway lists*

Chemicals to be excluded from initial testing

- Chemicals used as “positive controls” for assays
- Chemicals with low potential to cause endocrine disruption (e.g., strong mineral acids, certain FIFRA List 4 inerts)
- Chemical mixtures*
- Chemicals no longer produced or used in the US*

* May be addressed for future rounds of testing

Priority Setting Next Steps

- Use approach criteria to develop the draft initial list of chemicals to test first
- Emphasize this is not a list of “known” or “likely” endocrine disruptors
- Publish the draft list of chemicals for public comment in the Federal Register in Spring 2007
- Review comments and finalize list for Tier 1 screening by end of 2007

Current EDSP Activities



- Assay Validation - Development and validation of test assays (Tier 1 screening & Tier 2 testing)
- Priority Setting - Selecting chemicals to be screened
- **Procedures** - Developing implementation procedures for requiring testing

Procedures

- Purpose – Develop the processes and procedures the Agency will use to require testing under the EDSP
- Must have an ICR in place to require testing
- Statutory Authority – FFDCA Section 408(p)
- All documents will be available for public comment and will be finalized by the end of 2007 or early 2008

U.S. EDSP Timeline

2000 2001 2002 2003 2004 2005 2006 2007 2008 2009

