Endocrine Disruptor Screening Program (EDSP)

Presentation for

The Pesticide Program Dialogue Committee (PPDC)

October 7, 2008

EPA's Statutory Authority

The Food Quality Protection Act – August 3, 1996

- Amended the Federal Food, Drug, and Cosmetic Act (FFDCA)
  - Requires EPA to:

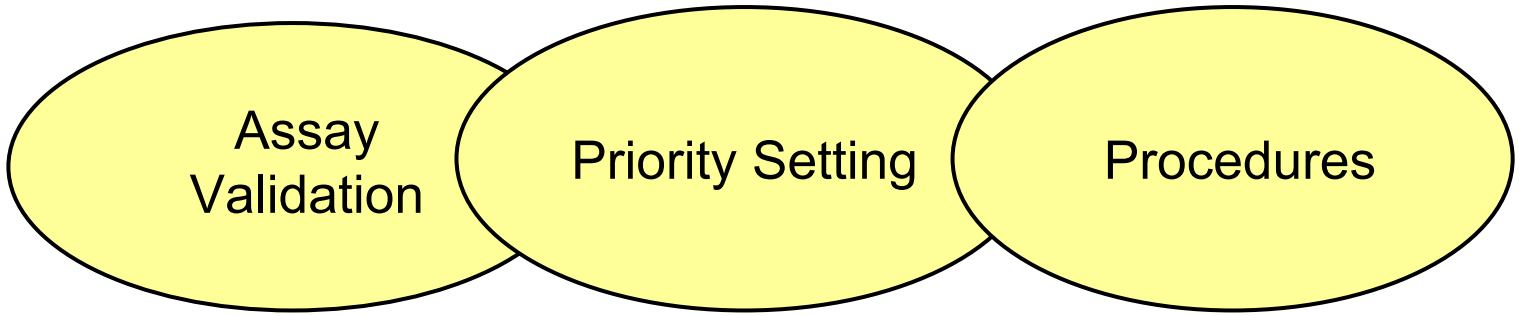
    "…*develop a screening program, using appropriate validated test systems and other scientifically relevant information to determine if certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen*…"

    provide for "…*testing of all pesticide chemicals*…"
  - Authorizes EPA to include:
    - *"…other endocrine effect[s], as the Administrator may designate*." (i.e., androgen and thyroid; endocrine effects in species other than humans)
    - Other non-pesticide chemicals that:
      - *"…may 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 following recommendations of:
  - The Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) of 1996-1998
  - Public comment
  - EPA's Science Advisory Board & FIFRA Scientific Advisory Panel

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 procedures to require and administer EDSP data

Assay Development & Validation

EDSTAC recommended a two-tiered approach

- Tier 1 battery (*in vitro* and *in vivo assays*)

  To identify substances that have the potential to interact with the estrogen, androgen, or thyroid hormone systems

- Tier 2 testing (multigenerational tests)

  To identify, and establish a dose-response relationship for any adverse effects that might result from the interactions identified through the Tier 1 assays

Tier 1 Screens

- 11 Assays to be included in the EDSP Tier 1 Screening Battery as proposed to the FIFRA Science Advisory Panel (SAP) March 25-27, 2008
  - Amphibian Metamorphosis (Complete)
  - AR Binding (Complete)
  - Aromatase (Complete)
  - ER Binding (2009-Q2)
  - ER Transcriptional Activation (Complete)
  - Female Pubertal (Complete)
  - Fish Screen (Complete)
  - Hershberger (Complete)
  - Male Pubertal (Complete)
  - Steroidogenesis (Complete)
  - Uterotrophic (Complete)
- The FIFRA SAP recommended using the Agency's proposed Tier 1 Screening Battery
  - FIFRA SAP Report Dated June 11, 2008

Tier 2 Tests

Assays Recommended by EDSTAC
Mammalian 2-generation
Avian reproduction
Amphibian Growth/Reproduction
Fish lifecycle
Mysid lifecycle

Note: The fact that a substance may be determined to interact with a hormone based on results from Tier 1 battery assays, does not mean it will cause adverse effects in humans or wildlife following Tier 2 testing.

Priority Setting
Approach

- Approach to selecting Chemicals for Initial Screening was established on Sept. 27, 2005, after considering comments
- Based on potential human exposure
  - Chemicals found in multiple pathways
    - Pesticide active ingredient presence in:
      - *Food*
      - *Water*
      - *Residential*
      - *Occupational*
    - High Production Volume (HPV) inerts in:
      - *Human and eco biomonitoring*
      - *Water*
      - *Air*

Priority Setting

Draft List → Final List

- Announced the Draft List of Chemicals for Initial Screening on June 18, 2007 in Federal Register Notice
  - Made available for public comment via docket
  - 64 Pesticide actives and 9 HPVs / pesticide inerts
  - Not a list of “known” or “likely” endocrine disruptors
- Public comment period ended on February 11, 2008
  - Public comment period had been extended 3 times
- Draft List revised after reviewing public comments
- The Draft Final List of Chemicals for Initial Screening has been submitted for Office of Management and Budget (OMB) review
  - “Response to Public Comments” Document also submitted for review

Policies & Procedures

FFDCA §408(p)(5) Directive

- Minimize duplicative testing
  - Promotes joint data development
  - “To the extent practicable”
- Develop, as appropriate, procedures for fair and equitable cost sharing
  - Promotes sharing of costs by joint data developers and data compensation by people who enter the marketplace after data are submitted
- Develop, as necessary, procedures for handling confidential business information

Policies & Procedures

Approach

- Generally, to require the submission of data under the EDSP, EPA intends to
  - Issue test orders under FFDCA §408(p)(5) and/or FIFRA §3(c)(2)(B)
  - Encourage the use of consortia to respond to orders
  - Adopt existing procedures to provide CBI protections and data compensation
- The Policies & Procedures outline
  - Format and general content for the test orders
  - How EPA will determine to whom orders will be issued
  - How order recipients should respond to orders, including procedures for challenging the orders

Policies & Procedures

Status

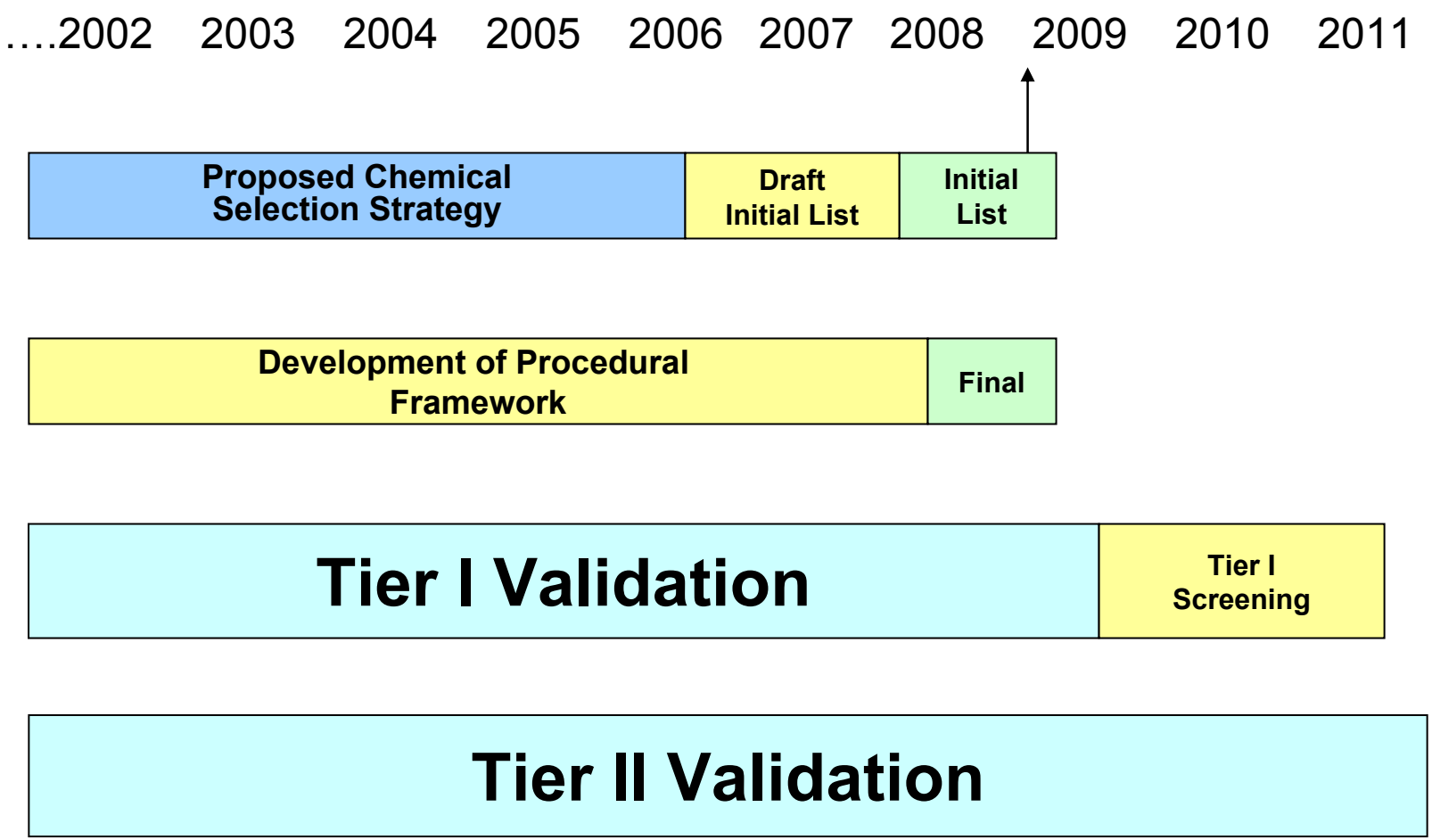
- Draft Policies, draft order templates & draft ICR issued on December 13, 2007
- Public comment period ended on March 11, 2008
- EPA has reviewed all comments and has prepared a “Response to Public Comments” document
- EPA has revised the Policies and Procedures in response to the comments
  - Submitted to OMB for review

Additional Stakeholder Questions/Comments*

- Request For Correction (RfC) submitted by the Center for Regulatory Effectiveness (CRE)
  - Submitted to EPA July 10, 2008
  - CRE requested that EPA make several corrections to the statements made in EPA's response to the Peer Review Results for the Amphibian Metamorphosis Assay
  - Response submitted to OMB for review
  - OMB has requested additional information
- CropLife America (CLA) submitted a petition to EPA regarding the EDSP
  - Submitted to EPA on July 11, 2008
  - Agency currently preparing response to the petition
  - Agency will submit the response for OMB review shortly
- OMB Meeting with the Physicians Committee for Responsible Medicine (PCRM)
  - Meeting held on July 16, 2008

***Received after all public comment periods had ended**

EDSP Timeline



For More Information

www.epa.gov/endo