

# EDSP -- Update

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Chemical Producers & Distributors Association  
2011 Spring Meeting

February 17, 2011

# TOPICS

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- History
  - Statutory Requirements
  - Development/Implementation of the EDSP
- EDSP Phase 1
  - Current Implementation Issues
- EDSP Phase 2 (List 2)
  - Arising Issues

# History

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- Statutory Requirements (1996)
  - Food Quality Protection Act -- FQPA §408(p)
    - Along with FIFRA, provides EPA's authority for requiring EDSP testing of pesticide chemicals
      - Includes Pesticide Inert Ingredients
    - FFDCA §408(p)
  - Safe Drinking Water Act Amendments
    - Provides EPA's authority for EDSP testing of non-pesticide chemicals
    - Uses implementation machinery of FQPA §408(p)

# Statutory Requirements

## FFDCA §408(p)(1) - Development

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. . . the Administrator shall . . . 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 such **other endocrine effect** as the Administrator may designate.

# ISSUES - Development

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- **“Screening Program”** –
  - EPA’s program likely exceeds Congressional intent, but more complete screening and testing will help to minimize false positive results.
  - E Screen - \$50/Chemical
  - EDSP – Tier 1: \$1M/Chem; Tier 2: \$3-5M/Chem
- Screens/tests must be **validated**.
  - Are the assays validated?
  - Is the Tier 1 battery validated
- **Human** testing only?

# Statutory Requirements

## FFDCA §408(p)(5) - Collection of Information

To the extent practicable the Administrator **shall minimize duplicative testing** of the same substance for the same endocrine effect, develop, as appropriate, procedures for fair and **equitable sharing of test costs**, and develop, as necessary, procedures for handling of **confidential business information**.

- Merely “qualified directives” as EPA claims?
- Significance -- Pesticides vs. Non-pesticides

# Noncompliance

## FFDCA §408(p)(5)(C) – Noncompliance by Registrants

- (i) Suspension of registration
- (ii) Hearing (only issue is whether party complied)
- (iii) Termination of suspension

## FFDCA §408(p)(5)(D) - Noncompliance by **other persons**

Any person (other than a registrant) who fails to comply with an **order** under subparagraph (A) shall be liable for the same penalties and sanctions as are provided under section **16 of the Toxic Substances Control Act** . . . .

- TSCA §16 provides for both civil (\$37,500 per day) and criminal (up to 1 year imprisonment and \$37.5K/day).

# Statutory Requirements

SDWA 42 U.S.C. §300j-17

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... the Administrator may provide for testing under the screening program authorized by section 346a(p) of title 21, in accordance with the provisions of section 346a(p) of title 21, of any other substance **that may be found in sources of drinking water** if the Administrator determines that a **substantial population may be exposed** to such substance.

## Issues - SDWA

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- EPA uses SDWA authority to require EDSP testing of non-pesticide chemicals.
- Note that this provision utilizes the procedures of FFDCFA § 408p.
  - The SDWA only adds substances to the provisions of the FFDCFA endocrine screening program.
  - **But, it is unclear from the language of the SDWA what additional substances may be added.**

# Issues - SDWA

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- “may be found in sources of drinking water”
  - What is meant by “may be found”?
  - What are “sources of drinking water”?
- “that a substantial population may be exposed to . . .”
  - What is a “substantial population”?
  - What is meant by “may be exposed”?
- EPA’s authority turns on the interpretation.

# Development of EPA's EDSP

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- Two Tiered Screening and Testing Program
  - Tier 1 Screening
    - Identifies substances with potential activity & flags for further testing
  - Tier 2 Testing
    - Identifies adverse effects and establishes dose-response relationship for hazard characterization and risk assessment
- Endocrine, Androgen and Thyroid
- Humans and Wildlife

# Implementation of Phase 1

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- Implementation of EDSP Phase 1
  - Final EDSP Policies and Procedures
    - 74 Fed. Reg. 17516, April 15, 2009
    - Non-binding Guidance
  - Final Listing for Initial Screening
    - 74 FR 17579, Apr. 15, 2009
    - 67 pesticide chemicals (active and inert ingredients)
  - Information Collection Request (ICR)
    - 74 FR 17477, Apr. 15, 2009
- Phase 1 Testing Orders Issued
  - From September 2009 – April 2010
  - Results due late 2011 to early 2012

# Implementation Issues

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- Problems assessing Other Scientifically Relevant Information (OSRI)
- Problems with Test Methods
- No real Weight-of-Evidence (WOE) Guidance
- Timing Issues

# OSRI

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- OMB Required EPA to consider OSRI
- No Agency Guidance
  - Hard to determine how EPA is assessing OSRI
  - EPA seems to be confused (by-pass option)
  - EPA was very slow to respond to OSRI waiver requests
    - Creates a timing issue
- Lack of Transparency
  - “Learn as we go” approach
  - Arbitrary?  
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# EDSP Implementation Issues

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- Problems with Required Test Methods
  - Test Orders are Prescriptive
  - Comments provided by Endocrine Policy Forum
    - Submitted comments in February 2010
    - Finally got a meeting with EPA in October 2010
    - EPA has still not responded
  - Creates a timing problem

# EDSP Implementation Issues

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- Weight of Evidence
  - EPA must develop WoE guidance for:
    - Determining whether tier 1 screens are positive
    - Triggering Tier 2
    - Determining whether a substance interacts with the endocrine system
  - EPA has not produced useful guidance

# Legal Considerations

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## ■ Basis for a time extension

- EPA's failure to provide a timely response to OSRI waivers
  - Confusion concerning Tier 1 bypass provides an additional basis
- EPA's failure to provide test method modifications
- Other problems as they arise
  - especially problems completing the assays
  - Laboratory capacity

## ■ Performing Tier 1 as a battery

- Shouldn't report results piecemeal
- EDSP has great potential for misuse, very expensive, EPA is "learning as it goes"

# EDSP Phase 2

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- Despite unresolved issues related to Phase 1, EPA is pushing forward with EDSP Phase 2
  - expansion of the EDSP from pesticides to chemicals that may be found in sources of drinking water
- Relevant Documents Published on Nov. 17, 2010
  - Draft Listing
  - Draft ICR
  - Draft policies and procedures
- EPA Plans to Issue Phase 2 Orders by the end of 2011
  - Phase 1 will not have been completed

# Overview of the Phase 2 Policies and Procedures

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- Test Orders will be sent to manufacturers and importers based primarily on TSCA Inventory Update Reporting Rule
  - 25,000 / site
  - Smaller manufacturers/importers off the hook?
  - Easy for EPA but is it fair?

# Response to an Order

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Recipient will have 90 days to respond.

Select one of the following options:

1. Indicate you intend to generate new data.
2. Indicate you are submitting or citing existing data (Other Scientifically Relevant Data)
3. Indicate you intend to enter (or offer to enter) into an agreement to form a consortium to provide the data
4. Claim you are not subject to the test order (e.g., you do not manufacture or import the substance)

# Response to an Order

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4. Indicate that you intend to discontinue all manufacture/import
5. Other Options:
  - 6a. Demonstrate with existing data the substance is a known endocrine disruptor
  - 6b. Demonstrate with existing data the substance “is not anticipated to produce an effect in humans similar to natural estrogen”
  - 6c. Chemical used as pos. control to validate an EDSP Tier 1 method

# Important Issues

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- EPA says it will assess Tier 1 data using its WoE process
  - What Process??
- Order recipient may offer OSRI to satisfy part or all of the Test Order
  - How will EPA assess OSRI?
  - Will EPA summarily dismiss OSRI - is it worth the effort?

# Important Issues

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- EPA has not yet defined key SDWA terms that define the Agency's authority
  - “may be found in sources of drinking water”
  - “that a substantial population may be exposed to . . .”
  - Arbitrary? Unfettered Authority?
- EPA relies on existing lists
  - CCL3; NPDWR (MCL); TRI
  - Meet Criteria? Then, Now
  - Sub no longer produced, Very small releases

# Important Issues

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- EPA Provides no CBI protections
  - Trade Secrets Act
  - FOIA
- EPA must provide a meaningful opportunity to submit OSRI
- EPA must develop meaningful WoE guidance

# Important Issues

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- EPA should limit orders to current manufacturers/importers
  - Should EPA provide the option to discontinue manufacture/importation?
  - How should EPA factor in persistence?
  - Should EPA's determination turn on its attempt to manage levels of chemicals in drinking water through test orders?

# Important Issues

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- Is EPA's data compensation plan sufficient?
  - What is to keep EPA from departing from its current non-binding plan?
  - Will EPA diligently enforce its plan?
- When must order recipients report risk data pursuant to TSCA 8(e) and FIFRA6(a)(2)

# Important Issues

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- EPA must ensure accurate and consistent communications across the agency offices and programs concerning the meaning of EDSP screening results
- EPA should not implement Phase 2 until it completes Phase 1