



Endocrine Disruption

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Endocrine Disruption

- ❖ Endocrine disruption is based on the premise that low-level environmental exposures to synthetic and naturally occurring hormonally active substances may interact with the endocrine system of wildlife and humans and cause adverse effects
- ❖ Global debates
 - Adverse wildlife effects
 - Accidental and unintentional human exposures
 - “Our Stolen Future” Theo Coburn’s book 1995/6
 - Alleged links to public health concerns – breast cancer, sperm counts, male and female reproductive diseases and developmental abnormalities

Concern About Endocrine Disruption Lead to Congress Passing Legislation in 1996 Mandating EPA to Establish an Endocrine Screening Program

❖ **1996 FQPA: Federal Food, Drug, and Cosmetic Act (FFDCA) required**

- EPA to develop a screening program using validated assays to identify pesticides that may have estrogenic effects in humans

❖ **1996 FQPA also authorized EPA to include:**

- Other endocrine effects, as designated by the EPA Administrator
- Other non-pesticide chemicals that may have “an effect cumulative to that of a pesticide

❖ **1996 Safe Drinking Water Act (SDWA) Amendments**

- Required testing of chemical substances found in drinking water, if a substantial human population may be exposed

Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC)

- ❖ April 1996 – EPA announced plans to develop a screening and testing program
 - 1995-1996 EPA conducted stakeholder/expert scientist workshops

- ❖ October 1996 – Federal Advisory Committee chartered
 - (www.epa.gov/scipoly/oscpendo)
 - 39 EDSTAC members represented a wide range of stakeholders
 - Government researchers and regulators, academia, NGOs, industry
 - Provided the opportunity for public comments at each session

EDSTAC Accomplishments

❖ Recommended a 2-Tiered, hierarchical approach

- Tier 1 – screening for endocrine activity (to prioritize for Tier 2 testing)
- Tier 2 – testing for adverse effects, dose response for risk assessment
- Estrogen, androgen and thyroid
- Human and ecological effects

❖ October 1998 – consensus report strongly supported the need for method validation

“The EDSTAC believes validation and standardization of the recommended screens and test are essential for the implementation of the EDSTP ...the validation and standardization program is of the highest priority, and recommends that it proceed on an accelerated schedule.”

Implementation of EPA's Endocrine Disruptor Screening Program (EDSP)

❖ US EPA

- 1999 EPA Policy Statement – adopting EDSTAC recommendations
- 1999 – Present EPA supports laboratory work to validate Tier 1 screens and Tier 2 tests
- 1999 – EPA's Science Board recommends the Agency tackle 50-100 substances initially, then re-evaluate
- 2005 – EPA finalizes priority setting process to select chemicals
- June 2007 - EPA announces draft list of chemicals for phase 1 EDSP (64 pesticide active ingredients, 0 HPV/inerts)
- December 2007 – EPA publishes proposed procedures for requiring testing and ICR
- March 25-28 EPA Science Panel meeting for Agency to get feedback on validation status of assays & advice on what assays should be grouped in the Tier1 Screening Battery