

*Journal of Toxicology and Environmental Health*, 49, pp. 409-438.

53. Tori, G.M., and L.P. Mayer (1981) "Effects of Polychlorinated Biphenyls on the Metabolic Rates of Mourning Doves Exposed to Low Ambient Temperatures." *Bulletin of Environmental Contamination and Toxicology*, 27, pp. 678-682.

## IX. Public Record and Electronic Submissions

The official record for this notice, as well as the public version, has been established for this notice under docket control number OPPTS-42208 (including comments and data submitted electronically as described in this unit). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 12 noon to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in Unit I.B.3. of this notice.

Electronic comments can be sent directly to EPA at:

oppt-ncic@epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number OPPTS-42208. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

## List of Subjects

Environmental protection, Chemicals, Drinking water, Endocrine disruptors, Hazardous substances, Health and safety, Pesticides and pests.

**Authority:** 21 U.S.C. 346a(p); 42 U.S.C. 300j-17; 7 U.S.C. 136a; 15 U.S.C. 2604.

Dated: December 21, 1998.

**Lynn R. Goldman,**

*Assistant Administrator for Prevention, Pesticides and Toxic Substances.*

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## ENVIRONMENTAL PROTECTION AGENCY

[OPPTS-42207; FRL-6052-8]

### Endocrine Disruptor Screening Program; Priority-Setting Workshop

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice invites public participation in a workshop to discuss the development of a priority-setting system for the selection of chemicals for testing in the Endocrine Disruptor Screening Program (EDSP). The recommendations of the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) and the Agency's subsequent Statement of Policy contain a set of principles and a general strategy for setting priorities for testing. The Agency is now commencing the detailed design phase of the priority-setting system and seeks public input on the design of the system.

**DATES:** The workshop will be held on Wednesday, January 20, 1999, from 10 a.m. to 5 p.m. and Thursday, January 21, 1999, from 9 a.m. to 4 p.m. Comments may be submitted during the workshop or after the workshop until February 22, 1999.

**ADDRESSES:** The workshop will be held at the Crystal City Marriott Hotel, 1999 Jefferson Davis Hwy., Arlington, VA; telephone (703) 413-5500, toll-free reservation line (800) 228-9290.

Comments should be sent to Patrick Kennedy or James Darr and to the OPPTS Document Control Officer. Comments may be sent electronically or by mail to: Patrick Kennedy, e-mail address: kennedy.patrick@epa.gov or Jim Darr, e-mail address: darr.james@epa.gov; Office of Pollution Prevention and Toxics (7406), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

Each comment must bear the docket control number OPPTS-42207. All comments should be sent in triplicate to: OPPTS Document Control Officer (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Room G-099, East Tower, Washington, DC 20460.

Comments and data may also be submitted electronically to: oppt.ncic@epa.gov. Follow the instructions under Unit V. of this notice. No Confidential Business Information (CBI) should be submitted through e-mail.

All comments which contain information claimed as CBI must be clearly marked as such. Three sanitized copies of any comments containing

information claimed as CBI must also be submitted and will be placed in the public record for this rulemaking. Persons submitting information on any portion of which they believe is entitled to treatment as CBI by EPA must assert a business confidentiality claim in accordance with 40 CFR 2.203(b) for each such portion. This claim must be made at the time that the information is submitted to EPA. If a submitter does not assert a confidentiality claim at the time of submission, EPA will consider this as a waiver of any confidentiality claim and the information may be made available to the public by EPA without further notice to the submitter.

**FOR FURTHER INFORMATION CONTACT:** For information related specifically to the workshop: Patrick Kennedy, telephone: (202) 260-3916, e-mail address: kennedy.patrick@epa.gov or Jim Darr, telephone: (202) 260-3441, e-mail address: darr.james@epa.gov; Office of Pollution Prevention and Toxics (7406), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. For general information or copies of the ESTAC Report: TSCA Hotline, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone (202) 554-1404, TDD (202) 554-0551; e-mail address: TSCA-Hotline@epa.gov.

## SUPPLEMENTARY INFORMATION:

### I. Background

The Agency first set forth the basic components of the EDSP in an August 11, 1998 (63 FR 42852) (FRL-6021-3) **Federal Register** notice. A more detailed Statement of Policy has been developed and is published elsewhere in this issue of the **Federal Register**.

The EDSP has five major components:

1. Sorting, in which chemicals are classified according to the availability of information on each chemical's endocrine-disrupting potential.

2. Priority setting, in which EPA will determine the priority order for entry into Tier 1 screening.

3. Tier 1 screening, a battery of *in vitro* and *in vivo* assays designed to identify those chemicals that are not likely to interact with the estrogen, androgen, or thyroid hormone systems (EAT).

4. Tier 2 testing, a battery of assays designed to determine whether a chemical may have an effect in humans similar to that of naturally occurring hormones and to identify, characterize, and quantify those effects for EAT effects.

5. Hazard assessment, a weight-of-evidence evaluation of Tier 1 and Tier 2 results.

It is expected that the sorting will result in a relatively small number of chemicals proceeding directly to Tier 2 testing or hazard assessment and that the vast majority of chemicals will be placed in priority setting for Tier 1 screening.

## II. Purpose and Structure

The purpose of the workshop is to provide stakeholders and experts in exposure and health and ecological effects an opportunity for input into the design and implementation of the priority-setting system. The focus of the workshop is to discuss the basic structure and functioning of the priority-setting system. Specifically, the workshop will address principles and approaches for developing rankings within compartments and for assigning overall weighting factors to the various compartments and information-related categories. The Agency does not intend to either present or react to specific lists of chemicals that could result from the various approaches that may be discussed.

The workshop will be structured around the discussion of specific issues by invited participants. A limited amount of time will be allotted for

additional comment by other meeting attendees. Participants may also submit written comments during the meeting or after the meeting. No formal registration for the workshop is required, but persons planning to attend are encouraged to notify the Agency contacts listed under "FOR FURTHER INFORMATION CONTACT" in this notice, preferably via e-mail, because space may be limited.

## III. Issues for Discussion

The EDSTAC recommended a "compartment-based priority setting strategy" that builds upon distinct exposure- and effects-related information categories and criteria as well as a category of specially targeted priorities. The EDSTAC listed the following information-related categories and subcategories of information that should be considered in developing the compartment-based approach.

### A. Exposure-Related Information

1. Biological sampling data
2. Environmental, occupational, consumer product, and food-related data (sampling and/or use data)
3. Environmental releases
4. Production volume
5. Fate and transport data and models

### B. Effects-Related Information

1. Toxicological laboratory studies and data bases
2. Epidemiologic and field studies and data bases
3. Predictive biological activity or effects models (e.g. SAR, QSAR)
4. Results of high throughput pre-screening (HTPS)

### C. Integrated Effects and Exposure Information

### D. Specially Targeted Priorities

1. Mixtures
2. Naturally occurring non-steroidal estrogens (NONEs)
3. Nominations

The EDSTAC did not reach agreement on the definition or weighting of specific compartments. Following the basic framework and guiding principles laid out in the EDSTAC Report, EPA has developed an initial "strawman" proposal for a compartment-based system. In developing the strawman proposal, EPA adopted the following working definition of a compartment: All chemicals within a compartment share the feature(s) that define the compartment (e.g. chemicals with TRI release data). The defining feature(s) of the compartment should, whenever possible, allow for sorting chemicals within the compartment into a rank-ordered list.

## PROPOSED COMPARTMENTS FOR EDSP PRIORITY SETTING

Specially targeted priorities	Exposure	Effects	Exposure and effects
Nominations .....	Human Biological Monitoring Data .....	Epidemiology and clinical data on endocrine target organ effects..	
EDSTAC Recommended Mixtures .....	Ecological Biological Monitoring Data .....	Reproductive/developmental toxicity—no observed adverse effect levels (NOAELs)/lowest observed adverse effect levels (LOAELs) from studies in laboratory animals..	
EDSTAC Recommended NONES .....	Chemicals in food and drinking water .....	Carcinogenicity—positive/negative results in endocrine target tissues.	
	Chemicals in consumer and cosmetic products	Subchronic toxicity—NOAELs/LOAELs for endocrine targets.	
	Occupational exposure chemicals	High Throughput Screen test results (degree of receptor binding).	
	Environmental monitoring data—Surface and ground water	Quantitative Structure—Activity Relationships (QSARs) for estrogen receptor binding.	
	Environmental monitoring data—Indoor and outdoor air	Ecotoxicity—field and laboratory studies.	
	Environmental monitoring data— Sediments/soil	.....	
	Persistence	.....	
	Bioaccumulation potential	.....	
	Environmental releases	.....	
	Production/import volume	.....	

The Agency has identified several key issues related to the design of a compartment-based priority-setting system. The Agency welcomes comment on these issues:

1. Do the exposure and effects compartments in the strawman proposal make sense? Are there other compartments that should be added?

Should certain compartments be combined, and if so, which?

2. How should exposure and effects data be integrated, combined in the exposure/effects category?

3. How should each of the major information-related categories (i.e. Exposure, Effects, and Exposure and Effects) be weighted? If they are not weighted equally, how much weight should each receive?

4. How should the compartments within each information-related category be prioritized relative to each other? What factors should be considered and how should they be used?

5. Do the exposure compartments allow for adequate consideration of disproportionately exposed and susceptible populations? How can this best be done?

6. Should a fraction of the chemicals screened be given priority status based solely on ecological concerns (as opposed to human health concerns)?

7. How should chemicals that occur in multiple compartments be treated, i.e. should the ranking system somehow

take into account frequency of occurrence across all compartments?

8. Should the specially targeted priorities, i.e. nominations, mixtures, and NONES, be included in the priority-setting system or should they be handled outside of the system?

9. What are the best data sources for the priority-setting system in terms of accessibility, reliability, and format?

#### IV. Agenda

January 20

Activity	Time
Welcome .....	10-10:15 a.m.
Background .....	10:15-10:30 a.m.
EPA Strawman .....	10:30-10:45 a.m.
General Comments and Questions on the Strawman .....	10:45-11:15 a.m.
Break .....	11:15-11:30 a.m.
Biological and Environmental Monitoring Data Compartments .....	11:30-12:15 p.m.
Lunch .....	12:15-1:30 p.m.
Persistence and Bioaccumulation Compartments .....	1:30-2:15 p.m.
Chemicals in Drinking Water and Food Compartment .....	2:15-3 p.m.
Break .....	3-3:15 p.m.
Consumer/Cosmetic and Occupational Compartments .....	3:15-4 p.m.
Relative Weights of Exposure Compartments .....	4-4:30 p.m.
Audience Comments .....	4:30-5 p.m.

January 21

Activity	Time
Epi/Repro/Cancer/Subchronic Health Compartments .....	9-10 a.m.
Ecological Effects Compartments .....	10-11 a.m.
Break .....	11-11:15 a.m.
QSAR .....	11:15-12 noon
Lunch .....	12 noon-1:15 p.m.
Relative Weights of Effects Compartments .....	1:15-1:45 p.m.
Combining Exposure and Effects .....	1:45-2:45 p.m.
Break .....	2:45-3 p.m.
Specially Targeted Chemicals .....	3-3:15 p.m.
Audience Comments .....	3:15-4 p.m.

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Dated: December 21, 1998.

Lynn R. Goldman,

Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.

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