Exposure Assessment for Chemicals Management

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ENVIRONMENTAL DEFENSE FUND

finding the ways that work

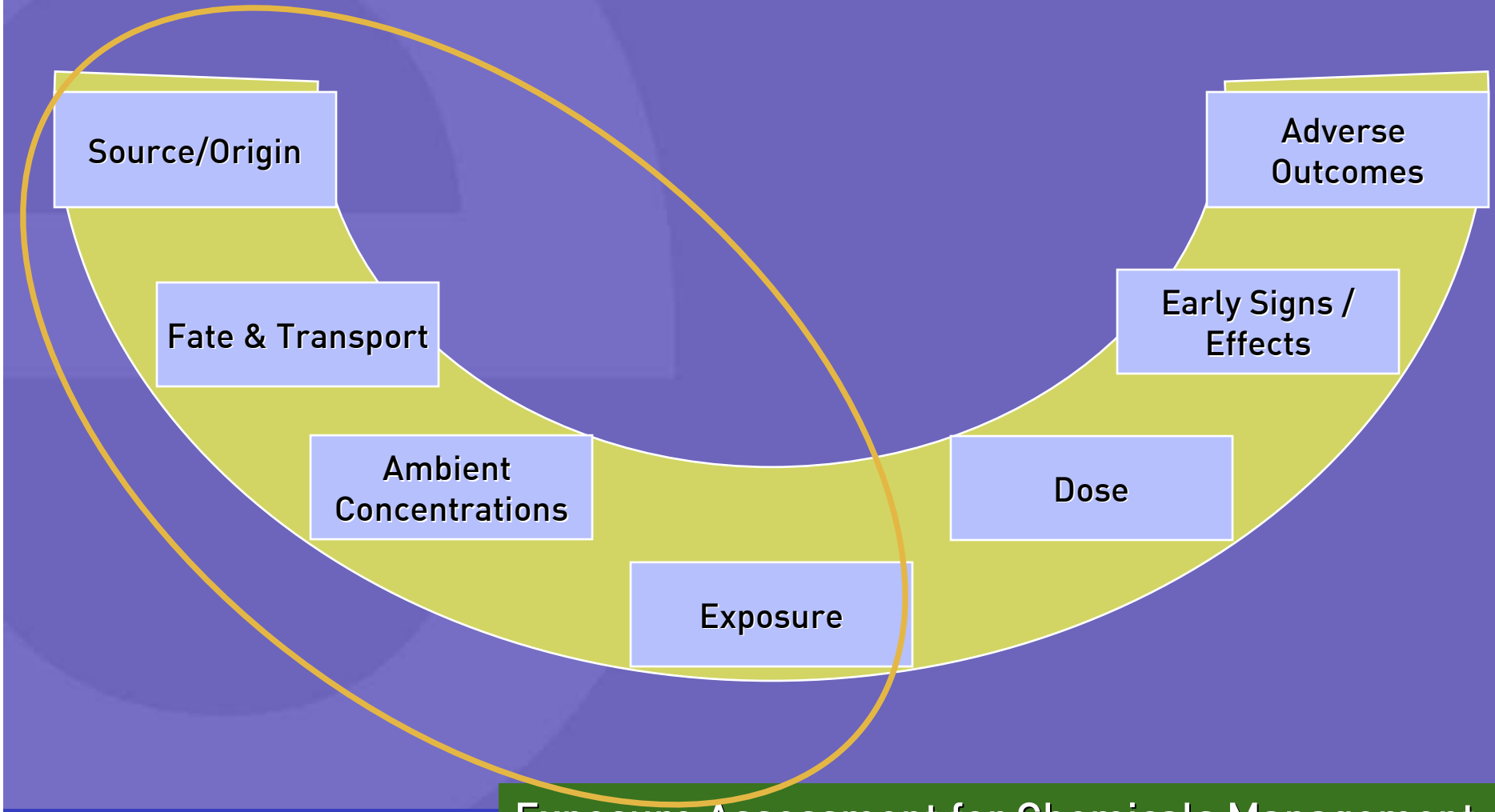
What Decisions are we Trying to Make?

- What chemicals pose significant risks to human health and the environment?
- Are safer chemical substitutes available?
- Should there be restrictions on the uses of certain hazardous chemicals to protect public health and the environment?

What Information do we Need to Answer these Questions?

- Hazard testing
- Physical & chemical properties
- List of all uses
- Environmental releases
- Exposure scenarios
- Assessment of aggregate exposures
- Consideration of similar chemicals (cumulative exposures)

Source to Dose Models



Exposure Assessment for Chemicals Management

How are Chemicals Used?

- Functional use, applications, & products types, use patterns
  - EPA use & exposure-related information
  - Public & private web resources
    - Household Products Database
    - Chemidex www.chemidex.com

Obstacles to Understanding Use

- No single source of information
- Lack of systematic tracking
- No integration within value chain
- Weak reporting requirements under TSCA
- Different regulatory authorities for different uses (EPA vs. FDA)

How is EPA Assessing Exposure for ChAMP? (an outsider's view)

http://www.epa.gov/champ/pubs/hpv/abouthpv.html#rbp

Exposure Characterization

- Qualitative and based largely on surrogates for exposure
  - Inventory Update Reporting
  - Production volume, number of sites, workers
  - Environmental releases/media
  - Physical/Chemical/Environmental Fate Characteristics
  - Known presence in environment
  - Public data, known uses
- Exposure categories: workers, environmental (humans, eco receptors), consumers, children
- Hampered by CBI and NRO claims.
- Absence of mechanisms for industry to collect pertinent information throughout value chain

Inventory Update Reporting

- Exposure-related information on chemical substances
- Current, nationwide set of information on the manufacturing and importation volumes of chemicals in quantities of ≥ 25,000 pounds per year.
- For chemicals produced or imported ≥ 300,000 pounds at an individual site, the 2006 IUR submissions also included some exposure-related information on processing and use.
- Made public to the extent possible, due to data confidentiality claims

2006 IUR Data Release

- **1) CHEMICAL (6,200 records) –Aggregated data for each chemical**
  - CAS #, CHEMICAL NAME
  - AGGREGATED PRODUCTION VOLUME
  - MAX CONCENTRATION
  - PHYSICAL FORM
  - NUMBER OF SITES
  - NUMBER OF WORKERS
  - CHEM IND_P (Text)
  - CHEM COMME (Text)

- **3) IND_ACTS (11,382 records) – Industrial processing and use information**
  - CAS #
  - PROCESSING TYPE
  - NAICS
  - INDUSTRIAL FUNCTION

- **2) COMPANY (24,669 records) – Company and site information** CAS (Text)
  - COMPANY
  - SITE NAME
  - SITE CITY, STATE. ZIP
  - MFR DATA
  - IMPORT DATA
  - SITE LIMIT

- **4) PROD_CAT (7,629 records) – Commercial and consumer use information**
  - CAS #
  - PROD CATEGORY
  - MAX CONC
  - CHILD USE

*Chemicals that have confidential or no reported industrial activity information will have null fields.

CAS #	PROCESSING	NAICS TITLE	INDUSTRIAL FUNCTION	PRODUCT CATEGORY	MAXIMUM CONC	CHILD USE
108-23-6	Processing as a reactant	Other Basic Organic Chemical Manufacturing	Intermediates			
108-24-7	Processing as a reactant	Artificial and Synthetic Fibers and Filaments Manufacturing	Other	Other	Greater than 90%	No
108-24-7	Processing as a reactant	Explosives Manufacturing	Other			
108-24-7	Processing as a reactant	Other Basic Organic Chemical Manufacturing	Intermediates			
108-24-7	Processing as a reactant	Pharmaceutical and Medicine Manufacturing	Intermediates			
108-24-7	Processing--repackaging	Other Basic Organic Chemical Manufacturing	Intermediates			
108-30-5	Processing as a reactant	Petrochemical Manufacturing	Intermediates	Other	Greater than 90%	No
108-31-6	NRO	NRO	NRO	Adhesives and sealants	NRO	No
108-31-6	Processing as a reactant	All Other Chemical Product and Preparation Manufacturing	NRO	Automotive care products	NRO	No
108-31-6	Processing as a reactant	All Other Chemical Product and Preparation Manufacturing	Surface active agents	Lubricants, greases and fuel additives	NRO	No
108-31-6	Processing as a reactant	Navigational, Measuring, Electromedical, and Control Instruments Manufacturing	NRO	NRO	NRO	NRO
108-31-6	Processing as a reactant	Other Basic Organic Chemical Manufacturing	Intermediates	Other	Greater than 90%	Yes
108-31-6	Processing as a reactant	Other Basic Organic Chemical Manufacturing	NRO	Rubber and plastic products	NRO	No

Worker Exposures

- Uses of the chemical
- Vapor pressure, physical state, concentration
- Estimated number of potentially exposed workers
- Production volumes
- Other factors such as the chemical's corrosive, flammable, and pyrophoric characteristics
- Availability of PELs, RELs, and TLVs
- Both inhalation and dermal contact are considered

Environmental Exposures

- Environmental releases and media of releases
- Physical/chemical properties (including volatility and solubility)
- Environmental fate characteristics, particularly persistence and bioaccumulation potential
- Production volume, the number of sites
- Known presence in the environment, if any, as demonstrated from monitoring data
- Down the drain uses

Commercial Workers, Consumers

- IUR reporting does not distinguish between commercial and consumer uses
- Assume consumer exposures are likely. Modified by additional information about consumer use, concentration and bioavailability
- When there is specific information indicating use in consumer products, default assumption is high potential consumers exposure
- Assume consumers do not use personal protective equipment or engineering controls to mitigate exposure

Children's Exposures

- Products specifically designed for children
- Consumer products that could possibly result in exposures through household use
- Uncertainty (e.g., NRO reports) in the IUR
- Consider reported use that may overlap with children's use, e.g., craft glue.

Assumptions and Uncertainties

- IUR production volumes and use information reported in 2006 are representative of current production volumes and uses
- Chemicals listed as closed-system intermediate (CSI) retain CSI status unless new information indicates otherwise.
- Recognized that there is uncertainty in the data reported in IUR regarding the industrial processing and use information re: number of potentially exposed workers, the number of sites, and use
- Submitters are required to only report use information to the extent that it is readily obtainable.

Data Confidentiality Claims

- Information submitted to EPA under the IUR regulation can be claimed confidential.
- Confidential Business Information (CBI) should meet the requirements set forth in 40 CFR Part 2, Subpart B, including the substantive criteria for use in confidentiality determinations at 40 CFR §2.208.

Not Readily Obtainable

- Lack of integration in the value chain means use information is not available to manufacturers.

Screening-Level Exposure Characterizations

- Qualitative Rankings
- CBI and Non-CBI Information Considered
- Does not include data that would allow the quantitative characterization of the magnitude, frequency, duration, or route of exposure.

Exposure Characterization Results

Exposure Rank	General Population	Workers	Consumers	Children
High or H/M	73	106	147	87
Moderate	98	65	8	52
Low	39	39	55	71
Not assessed	2	2	2	2
Total	212**	212**	212**	212**

**Data not submitted for 8 chemicals

Lack of Transparency Hinders Evaluation

- Extent of use and exposure information available to EPA is being denied and not transparently communicated to the public
- Deference to the extensive claims of confidential business information (CBI) made for such information
- Failure to clearly indicate what specific reportable information elements were not submitted because they were not "readily obtainable" by the manufacturer

Critique of Children's Exposure Evaluation

- Aggregate exposures not adequately considered:
  - Environmental exposures + consumer products + children's products
  - Increased vulnerability of children
    - Greater exposures
    - Sensitivity, susceptibility

What's Available Online?

EDF's Use Project

Methods

- Search publicly accessible databases in US and Europe
  - HPV, ChAMP
  - OECD HPV
  - ChemID Plus and Linked Websites
    - Hazardous Substances Data Bank (HSDB)
    - Household Products Database
  - WHO/IPCS/CICADS
  - Canadian DSL
  - European chemical Substances Information System (ESIS)/Online Risk Assessment Reports (ORAR)
- ~ 30 Chemicals identified by European NGO ChemSec as "SIN" Chemicals (http://www.chemsec.org/list)

1,2,4-Trichlorobenzene

(CAS# 120-82-1)

- Uses/Products
  - No information in HPV/ChAMP (supporting chemical)
  - OEHAA: Solvent in chemical manufacturing, an intermediate in the production of other chemicals, a component of dielectric fluids, and as dye carriers, degreasing agents and lubricants (HSDB, 1998). It is also used as an herbicide for aquatic weed control in irrigation canals, lakes, and ponds
  - OECD HPV: Intermediate in closed systems for the manufacture of herbicides and higher chlorinated benzenes. Process solvent, dye carrier, metal working fluids, dielectric fluids and heat transfer medium.
  - HSDB: Solvent in chemical manufacturing, dyes & intermediates, dielectric fluid, synthetic transformer oils, lubricants, heat-transfer medium, insecticides. Co-monomer in the production of polymers.... Used in degreasing agents, septic tank and drain cleaners, wood preservatives, and abrasive formulations.
  - CICAD: Dye carriers, degreasing solvents, oil additives, and dielectric fluids and in the formulation of pesticides. Chlorobenzenes are used mainly as intermediates in the synthesis of pesticides and other chemicals.
  - ORAR: Used in pesticide production, and in textile, iron, and metal industries. In the Nordic countries 1,2,4-TCB is only registered in few products for the following uses:
    - cooling agent and lubricant in the metal industry,
    - additive in polish and maintenance products,
    - anti-corrosives paint or rust removing agent (corrosion inhibitor - use category 14).

    UK: used in manufacture of high performance insulation for use in wire and cable products (3 to 4 tonnes annually) and a much smaller use (300 kg annually) as a blend in the production of a brightener solution for use in lead/tin plating baths.

1,2,4-Trichlorobenzene
(CAS# 120-82-1)

- % Use
  - ORAR: The use can be broken down into use for (BUA, 1987):
    - 40-60% used as an intermediate
    - ←5% dye carrier in the textile industry
    - ←5% as a solvent or extraction
    - 30-50% exported outside the EU
  - ORAR: Based on main manufacturer information (1996), the breaking down of the yearly consumption
    - 1,100 tonnes (79%) used in industry as an intermediate and
    - 200 tonnes (14%) used in industry as a process solvent and
    - 100 tonnes (7%) are used as a dyestuff carrier, lubricant, additive and other minor uses.

Galaxolide

(HHCB= 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethyl cyclopenta[g][2]benzopyran) (CAS# 1222-05-5)

- Uses/ Products
  - HPV IUR: 1-10 million pounds; child use NRO
  - HPV/ChAMP: Fragrance formulations of a wide variety of consumer products ranging colognes and eau de toilettes to soaps and detergents. Viscous material commonly sold and used as ~65% dilution in a neutral solvent.
  - HSDB: Synthetic, artificial musk fragrance; Fragrance ingredient in perfumes, soaps, cosmetics, and detergents.
  - IUCLID: Personal and domestic use, public domain, cleaning/washing agents and disinfectants. Cosmetics. Odor agents.
  - ORAR: Perfumes, cosmetics, soaps, shampoos, detergents, fabric conditioners, household cleaning products, air fresheners etc...

Galaxolide

(HHCB= 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethyl cyclopenta[g][2]benzopyran) (CAS# 1222-05-5)

- % Usage
- HSDB: In public use since 1960s. Use in fragrances in the USA exceeds 50,000 lb/yr. Concentration in final product: soap 0-15% , detergent 0-015% [sic, typo?], creams, lotions 0-10%, and perfume 0-3% (RIFM 2003)
- ORAR: Detergents 25%; fabric softeners 14%; soaps 9%; bath & shower 10%; industrial and household cleaners 8%; hair care 10%; personal care 13%; fine fragrances 5%; other 6%. (Balk et al. 2001)

Use Project Findings

- Publicly available information on chemical use is highly variable in quantity and quality
- Detailed risk-based prioritization decisions are not yet feasible

What Decisions are we Trying to Make?

- What chemicals pose significant risks to human health and the environment?
- Are safer chemical substitutes available?
- Should there be restrictions on the uses of certain hazardous chemicals to protect public health and the environment?
  - Additional Studies - Use Restrictions
  - Monitoring/biomonitoring - Banning

Exposure Assessment for Chemicals Management

Do we have the Information to Answer these Questions?

- ✓ Hazard testing (with some gaps)
- ✓ Physical & chemical properties
- □ List of all uses (some uses available)
- ✓ Environmental releases (many chemicals)
- □ Exposure scenarios
- □ Assessment of aggregate exposures
- □ Assessment of cumulative exposures

What Can We Do Now?

SORT:

Function

NAICS

Processing

RESULT:

Similar use profile

NEXT STEPS:

Evaluate hazard

CAS	PROC_TYPE	NAICS_TITL	IND_FUNCTI
100-42-5	Processing as a reactant	Adhesive Manufacturing	Adhesives and binding agents
103-11-7	Processing as a reactant	Adhesive Manufacturing	Adhesives and binding agents
105-44-2	Processing as a reactant	Adhesive Manufacturing	Adhesives and binding agents
108-05-4	Processing as a reactant	Adhesive Manufacturing	Adhesives and binding agents
108-95-2	Processing as a reactant	Adhesive Manufacturing	Adhesives and binding agents
110-85-0	Processing as a reactant	Adhesive Manufacturing	Adhesives and binding agents
124-04-9	Processing as a reactant	Adhesive Manufacturing	Adhesives and binding agents
13822-56-5	Processing as a reactant	Adhesive Manufacturing	Adhesives and binding agents
141-32-2	Processing as a reactant	Adhesive Manufacturing	Adhesives and binding agents
1760-24-3	Processing as a reactant	Adhesive Manufacturing	Adhesives and binding agents
25013-15-4	Processing as a reactant	Adhesive Manufacturing	Adhesives and binding agents
2530-83-8	Processing as a reactant	Adhesive Manufacturing	Adhesives and binding agents
26896-20-8	Processing as a reactant	Adhesive Manufacturing	Adhesives and binding agents
2768-02-7	Processing as a reactant	Adhesive Manufacturing	Adhesives and binding agents
50-00-0	Processing as a reactant	Adhesive Manufacturing	Adhesives and binding agents
57-13-6	Processing as a reactant	Adhesive Manufacturing	Adhesives and binding agents
78-08-0	Processing as a reactant	Adhesive Manufacturing	Adhesives and binding agents
8002-26-4	Processing as a reactant	Adhesive Manufacturing	Adhesives and binding agents
82985-35-1	Processing as a reactant	Adhesive Manufacturing	Adhesives and binding agents
919-30-2	Processing as a reactant	Adhesive Manufacturing	Adhesives and binding agents
924-42-5	Processing as a reactant	Adhesive Manufacturing	Adhesives and binding agents
96-33-3	Processing as a reactant	Adhesive Manufacturing	Adhesives and binding agents
98-00-0	Processing as a reactant	Adhesive Manufacturing	Adhesives and binding agents

(Short) Wish List

- Integrated assessment of risk by functional uses and applications to facilitate green chemistry choices
- Ability to collect more detailed use information for high & moderate hazard chemicals
- Consideration of aggregate and cumulative exposures in risk assessments
- More detailed consideration of children's exposures & vulnerabilities