

**Presentation to Biomonitoring California
Scientific Guidance Panel**

**Biomonitoring &
Consumer Product Regulation
in California**

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Among the uses for CA biomonitoring data:

Determining human exposure to state-regulated chemicals in consumer products & improving regulatory responses



Who regulates consumer products sold in CA?

- **Federal: CPSC (articles), EPA (pesticides), FDA (foods, drugs, cosmetics)**
- DTSC (Safer Consumer Products regulations)
- CDPH (Sherman Law & Safe Cosmetics Act)
- ARB (consumer product regulations – VOCs, toxics, GHGs)
- DPR (retail pesticides — in-home, repellents, lawn & garden)
- OEHHA & DOJ (Proposition 65)
- BEARHFTI (flame retardants - home furnishings)
- Office of the State Fire Marshall (flame retardants – other)

... and likely others

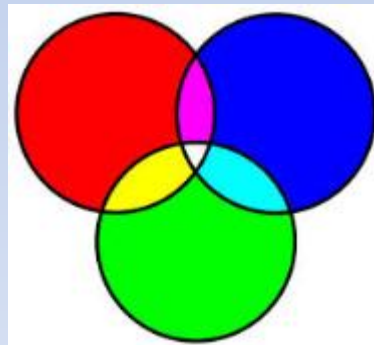
What consequences flow from biomonitoring data indicating exposure?



Concept without percept is blind;
Percept without concept is empty.

- *Immanuel Kant*

State agencies' jurisdiction over products



Department of Toxic Substances Control (DTSC)

AB 1879 & Safer Consumer Products regulations:

- Identify Candidate Chemicals
- Identify Priority Products and their Chemical(s) of Concern
- Require Alternatives Analysis
- Impose Regulatory Response(s)

Statute ~ Regulations should consider as one of three key prioritization factors:

- “The potential for exposure to the chemical in a consumer product” [Health & Saf. Code § 25252(a)(2)]

Regulations ~ Explicit use of biomonitoring evidence in prioritization:

- Priority Chemicals in CA Biomonitoring Program, & chemicals biomonitoring by federal CDC, automatically become Candidate Chemicals [22 Cal. Code Regs. § 69502.2(a)(1)(F),(G)]

Additional uses (implicit):

- Determining cumulative effects, identifying preferentially exposed or sensitive subpopulations [22 Cal. Code Regs. § 99503.3(a), (b)]

Biomonitoring data were partial justification for 2 of 3 initial products proposed:

- *Methylene chloride in paint strippers*
- *Chlorinated Tris (TDCPP) in children's sleep products*

California Department of Public Health (CDPH)

CA Safe Cosmetics Act (Health & Saf. Code § 111791 et seq.)

- Requires companies to disclose to CDPH any ingredients in cosmetics sold in CA that are identified as causing cancer, birth defects, or other reproductive harm (“Proposition 65+”)

CDPH has authority to:

- Investigate reported cosmetic products
- Review health effects data, “exposures to individuals in various settings”
- Require manufacturer submittal of:
 - ❖ health effects information
 - ❖ chemical concentration data
 - ❖ sales & use data for occupational settings

Sherman Food, Drug, & Cosmetic Law

CDPH has authority to:

Set tolerances (including, zero) for “poisonous or deleterious substances,” color additives (Health & Saf. Code § 110070)

Air Resources Board (ARB)

Consumer Product Regulations - *address air emissions from products*

- Most address volatile organic compounds (VOCs), due to smog concerns
 - VOC Standards for Consumer Products encompass, *e.g.*: adhesives, degreasers, cosmetics, flooring, home/general purpose/auto cleaners, air freshener, fabric softeners, cooking spray (17 CCR § 94509 (a))
- Some regulations address Toxic Air Contaminants
 - Methylene chloride, PCE, TCE prohibited in many uses; PDB & alkylphenol ethoxylate prohibited in some uses (17 CCR § 94509(m))
- Some address Global Warming Potential (GWP), specified as a number value
 - No products in specified categories (*e.g.*, paint thinning) may exceed indicated GWP value (17 CCR § 94509(n))

Product survey in update process, encompassing hundreds of consumer & commercial products; formal survey to be initiated August 2014

Department of Pesticide Regulation (DPR)

All pesticides sold in CA require state registration.

(Food & Ag. Code § 12811.)

Consumer pesticide products include:

- Home-use biocides (rodenticide, insecticide, herbicide)
- Marine anti-fouling paints

DPR may refuse / cancel registration independent of EPA.

Recent example based on biomonitoring data in animals:

- Effective July 1, 2014: Ban on anti-coagulant rodenticides with brodifacoum, bromadiolone, difenacoum, or difethialone.

Rationale: “DPR passed the regulation to ban the sale of pesticide products to consumers as it wants to protect wildlife. **These poisons have been found in a variety of animals** including barn owls, coyotes, bobcats and the San Joaquin kit fox (an endangered species).”

-DPR Press Release

Office of Environmental Health Hazard Assessment (OEHHA)/Department of Justice (DOJ)

PROPOSITION 65 “Right to Know” law (Health & Saf. Code § 25249.5 *et seq.*)

- OEHHA maintains the Proposition 65 list, which includes hundreds of chemicals known to cause cancer or reproductive toxicity
- DOJ, and other public and private enforcers, may file suit where products cause exposure without prior warning
- Defendant must prove the exposure is below the regulatory “safe harbor”
- Fact/extent of exposure usually hotly contested

=> Biomonitoring data helpful in:

- Prioritizing public enforcement
- Evaluating data in support of private enforcement

Many other agencies' actions indirectly affect the composition
of consumer products sold in California,
for example

Bureau of Electronic Appliance Repair, Home Furnishings and Thermal Insulation (BEARHFTI)

Establishes flammability performance standards for articles of home furnishings; these standards may induce use of additive chemical flame retardants.

Office of the State Fire Marshall

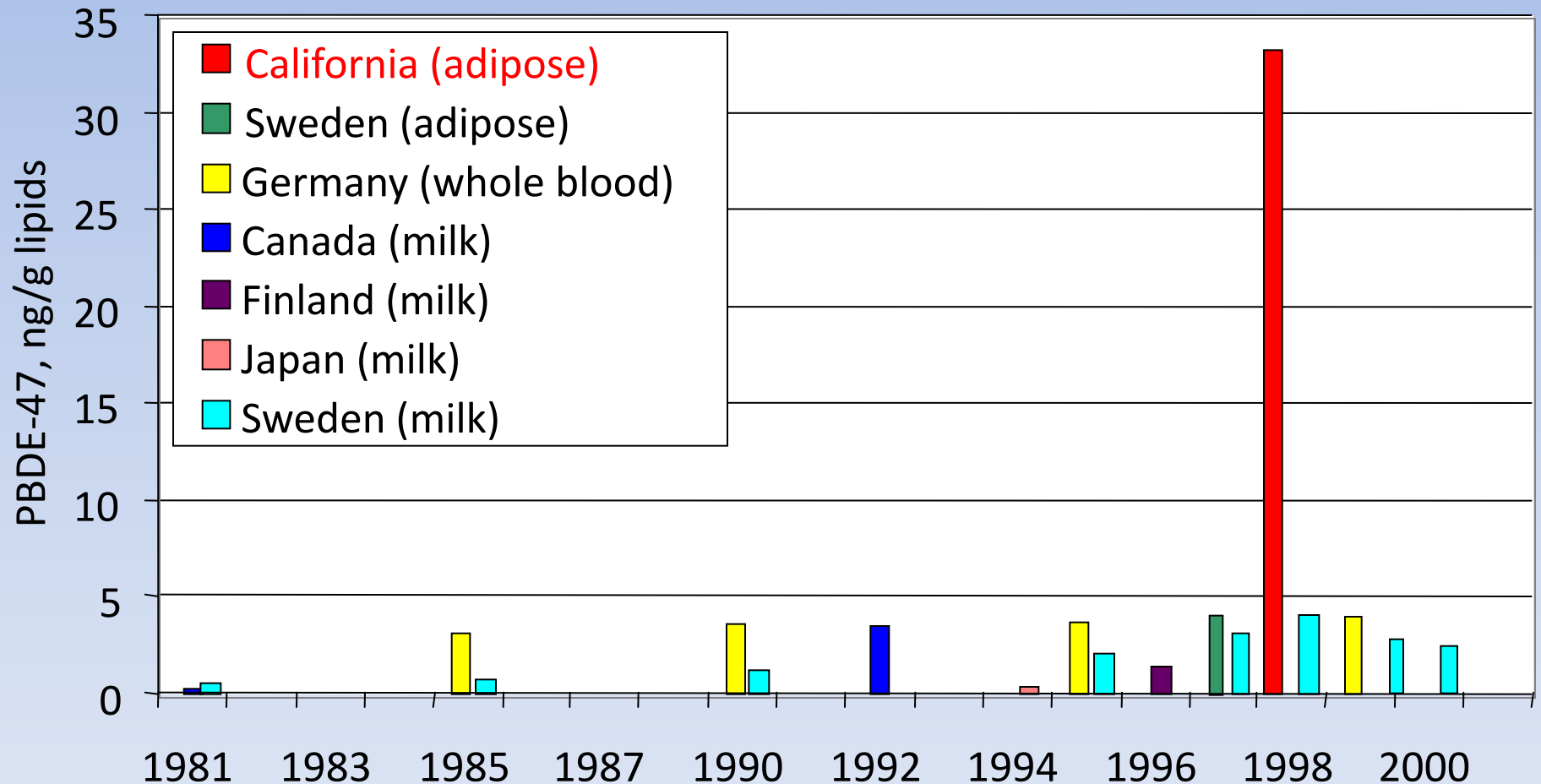
Registers and approves chemicals for use in fire-retarding fabrics and decorative materials in most public spaces, including, *e.g.*, jails, schools, and hospitals. No consideration is given to these chemicals' toxicity.

ENGAGE PRODUCT-REGULATORY AGENCIES
AT STUDY DESIGN STAGE TO:

- 1. Use their regulatory expertise**
- 2. Create a back-end audience for
biomonitoring data**

The Importance of NON-TARGETED SCREENING

PBDE-47 in Human Tissues



CA data from Petreas *et al.* (2001)

Are we most concerned about the right things?



lead



phthalates



formaldehyde



BPA

pesticides



The value of non-targeted screening



Halogenated FRs



END