What's Up with TSCA Reform

Richard A. Denison, Ph.D.
Senior Scientist

Presentation at workshop on
Environmental Influences on Neurodevelopment

January 12, 2012
UCLA

EDF
ENVIRONMENTAL DEFENSE FUND™
Finding the ways that work

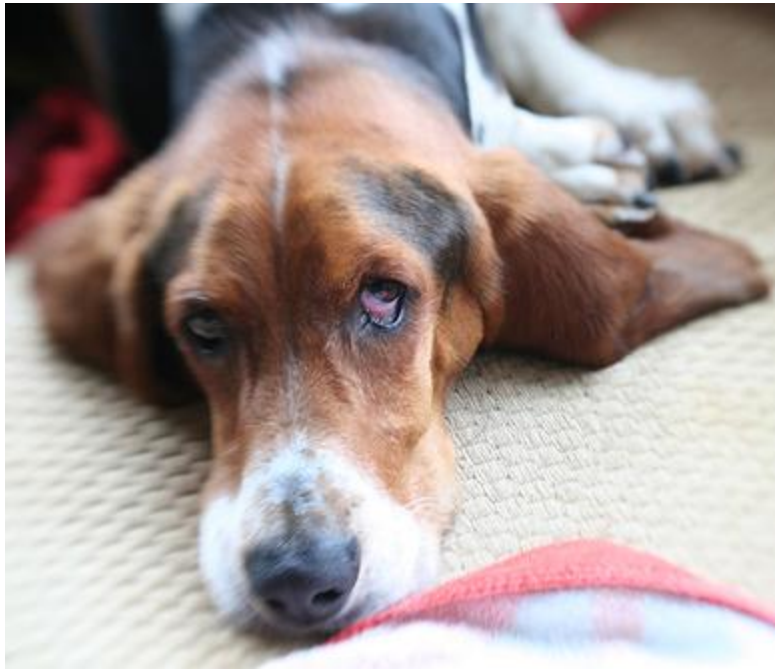
TSCA

- “Chemical of concern” = “unreasonable risk”
- Burden on government to evaluate:
  - health & environmental effects and exposure,
  - benefits of the chemical,
  - the availability of substitutes, and
  - economic costs, benefits of regulation
- Must also show by “substantial evidence” that:
  - the proposed control is least onerous
  - no other statute could address the concern

TSCA

- No statutory and few regulatory criteria; usually presented as general guidelines to be applied on case-by-case basis
- Little transparency or clarity as to how USEPA decides which chemicals are of concern, how safety is assessed or when risk assessment/management are needed
- No specification of types/extent of data needed to show safety

TSCA, the Dog that Didn't Even Bark



By the numbers:

- **62,000** chemicals grandfathered in when TSCA was passed in 1976
- Required testing on **<300** in 35 years
- **5** chemicals have been regulated in limited ways
- **19 years** since EPA last tried (and failed) to regulate a chemical: *asbestos*

U.S. Legislation: Current and Proposed

- Toxic Substances Control Act of 1976 (TSCA)
  - Covers most chemicals used in industry and in commercial/consumer products
  - Excludes:
    - uses in drugs, cosmetics, food packaging regulated by FDA
    - uses in pesticides covered by EPA under FIFRA
- Reform legislation: *Safe Chemicals Act* of 2011 (S. 847)
  - Introduced by Senators Lautenberg, Schumer, Franken, Klobuchar and Boxer
  - Co-sponsors: Blumenthal, Durbin, Gillibrand, Leahy, Menendez, Merkley, Sanders, Whitehouse, Feinstein

Incorporating the latest science into chemical policy

- Safety data requirements
  - Multiple approaches to filling gaps
  - Emerging methods via Tox21
- Use of risk assessment
  - Science behind RA has evolved and will continue to do so: NRC reports *Science and Decisions*, *Cumulative Assessment of Phthalates*
  - Key needs: Addressing uncertainty, variability, co-exposures

Improving Risk Assessment

- EPA is increasingly asked to address broad public- and environmental-health issues inadequately captured by current risk assessments
  - multiple exposures
  - complex mixtures
  - vulnerability of exposed populations
- There is a need for risk assessments that include
  - aggregate exposure to a given agent or stressor
    - all routes, pathways, and sources of exposure
  - combined risks posed by cumulative exposure to multiple agents or stressors
  - chemical and non-chemical stressors

Safe Chemicals Act of 2011 (S. 847)

Safety standard is to:

- be based "*solely on considerations of human health and the environment*, including the health of *vulnerable human populations*."
- provide a "*reasonable certainty that no harm* will result to human health or the environment from *aggregate exposure* to the chemical substance"
- "*to the extent practicable*, review and incorporate any available scientific information relating to the effect of *cumulative exposure* to that chemical substance on human health and the environment"

Aggregate Exposure (S. 847)

All exposures to a chemical substance or mixture from the manufacture, processing, distribution, use, and disposal and from—

- contamination of food, air, water, soil, and house dust from current or prior uses or activity;
- accidental releases;
- permitted sources of pollution;
- nonpoint sources of pollution; and
- documented background levels from natural and anthropogenic sources.

Cumulative Exposure (S. 847)

The sum of aggregate exposure to each of the chemical substances that are known or suspected to contribute appreciably to the risk of the same or a similar adverse effect.

Vulnerable Human Population (S. 847)

A population that is subject to a disproportionate exposure to, or potential for a disproportionate adverse effect from exposure to, a chemical substance or mixture, including—

- infants, children, and adolescents;
- pregnant women;
- the elderly;
- individuals with preexisting medical conditions;
- workers; and
- members of any other appropriate population identified by the Administrator

NAS recommendations (S. 847)

The Administrator shall:

- Use the best available science when conducting an assessment
- For the purpose of determining the current best available science the Administrator shall base the determination on the recommendations of the National Academy of Sciences in the report entitled ‘Science and Decisions.’

Where there's agreement

EPA / ACC / SCHF principles all agree that:

- TSCA's cost-benefit standard needs to change
- New safety standard should:
  - be strictly health-based
  - generally be applied via risk assessment
  - account for uses of a chemical
  - incorporate newest/best science
  - apply to vulnerable populations
  - consider full lifecycle
- Safety assessment should be separate from risk management
  - latter is where benefits/costs, alternatives, socioeconomic factors, etc. are to be considered

Where there's not (or less) agreement

- Aggregate exposure – when is it needed?
- Cumulative exposure – is it needed? is it feasible?
- Non-TSCA uses/sources – what's in, what's not?

Safer Chemicals Healthy Families (SCHF) position

- Safety determinations using risk assessment:
  - must incorporate NAS recommendations
  - should not preclude expedited action on PBTs and other very high-concern chemicals with widespread exposure
- Inclusion of *aggregate exposure* critical to reflect real world and disproportionate exposures
- *Cumulative exposures*:
  - can be done now for some classes of chemicals
  - must be required where feasible in a TSCA that is to have some shelf life and adapt to evolving science

SCHF's position (cont'd)

- *Aggregate exposures* should include:
  - uses regulated under current TSCA
  - uses regulated under other statutes or by other agencies
  - legacy sources (e.g., contaminated sites, waste sites)
  - direct releases to the environment
  - exposure to contaminated food, water, air, dust
  - both intended and reasonably anticipated exposures

SCHF's position (cont'd)

Level of assessment and data needed:

- The safety standard itself, i.e., the level of safety required, should *not* differ among different chemicals or their uses.
- Rather, the required depth and scope of assessment may be varied to fit the nature of the chemical, its uses and exposures.
- Likewise, the types and amounts of hazard data needed to conduct the assessment may vary.

Data requirements (S. 847)

- Minimum data sets for all new and existing chemicals
  - Level of data can vary based on use, etc.
- Can require information on
  - carcinogenesis, mutagenesis, teratogenesis, behavioral disorders,
  - cumulative or synergistic effects, and
  - exposure including presence in human blood, fluids, or tissue; and
  - bioaccumulation or persistence;
  - acute, subacute or chronic toxicity; or
  - any other characteristic which may present an adverse effect.
- Adverse effects include
  - mortality, morbidity
  - effects on
    - reproduction or growth and development
    - the immune, endocrine, brain or nervous system, or other organ systems
    - any other biological functions

Prenatal and Infant Exposures (S. 847)

Requires that, for chemicals that may be in people and may adversely affect early development:

- CDC is to biomonitor to determine if pregnant women/infants are exposed.
- If so, manufacturers and processors must publicly disclose all known uses of the substance and articles in which the chemical is expected to be present.

RECENT DEVELOPMENTS

For more information

EDF's Chemicals Policy Webpage
www.edf.org/health/policy/chemicals-policy-reform

Safer Chemicals, Healthy Families
www.saferchemicals.org

Not a Guinea Pig
www.notaguineapig.org

EDF Chemicals & Nanomaterials Blog
www.edf.org/chemandnano