

The Toxic Substances Control Act (TSCA); One of the most influential regulatory levers to remove toxic chemicals from building and consumer products

Case Study: Formaldehyde & Asthma

March 9, 2023

I have no conflicts to disclose



Our system to regulate toxic chemicals is not working and puts people and communities in harms way



V



Toxic Substances Control Act



What is TSCA?

- Enacted in 1976 to give EPA authority to regulate chemicals in commerce
- Covers all chemicals except for categories like drugs, cosmetics, food additives, and pesticides
- Chemicals already in commerce were/still are assumed to be safe until shown harmful
- In 40 years between original TSCA & 2016 amendments, EPA regulated < 10 of over 86 000 chemicals registered for use in commerce



Amended TSCA requires EPA to:

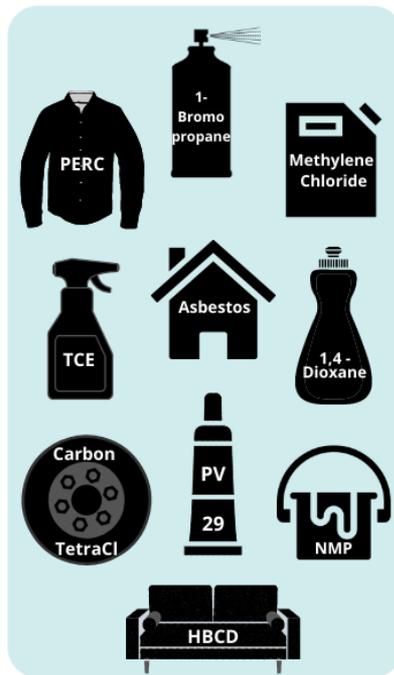
- Consider risks to “**potentially exposed or susceptible subpopulations**” (**PESS**) and determine if a chemical poses an “**unreasonable risk**” without consideration of cost
- Regulate any existing chemical determined to pose an unreasonable risk “**to the extent necessary so that the chemical substance or mixture no longer presents such risk**”
- Use “information, technical procedures, measures, **use scientific methods**, protocols, methodologies, or models, employed in a manner **consistent with the best available science**”



But....
TSCA is
Broken

Since EPA's implementation of amended TSCA there have been:

10 Final Risk Evaluations



with

5

major problems where
EPA underestimated
risk and could harm
public health

We recommend that EPA



Consider All Conditions of
Use and Exposure Pathways



Quantify Exposures
Across Pathways and
Populations



Better Identify and Protect
Potentially Exposed or
Susceptible Subpopulations



Gather Health and Toxicity
Data to Fill Data Gaps



Use a Valid Systematic
Review Method



p-Dichlorobenzene	Di-isobutyl phthalate (DIBP)
1,2-Dichloroethane	Dicyclohexyl phthalate
trans-1,2- Dichloroethylene	Dibutyl phthalate (DBP)
o-Dichlorobenzene	Butyl benzyl phthalate (BBP)
1,1,2-Trichloroethane	Di-ethylhexyl phthalate (DEHP)
1,2-Dichloropropane	Ethylene dibromide
1,1-Dichloroethane	1,3-Butadiene
4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA)	HHCB
Tris(2-chloroethyl) phosphate (TCEP)	Formaldehyde
Phosphoric acid, triphenyl ester (TPP)	Phthalic anhydride

Next 20 High Priority Chemicals EPA is evaluating

Chlorinated solvents

Flame retardants

Phthalates

The Problem

Under Amended TSCA EPA must use the best available science to evaluate the impact of toxic chemicals and make decisions that protect human health and the environment

However...

EPA currently has **no method to quantify health risks for non-cancer effects of toxic chemicals**... so they can't quantify the health risks of outcomes like asthma, diabetes, dementia, CVD etc



Health risk from environmental chemical exposure is assessed differently for **cancer** versus **non-cancer** health effects

Non-cancer Health Effects:

There are “safe”^{*} exposure levels that don't increase risk of disease.

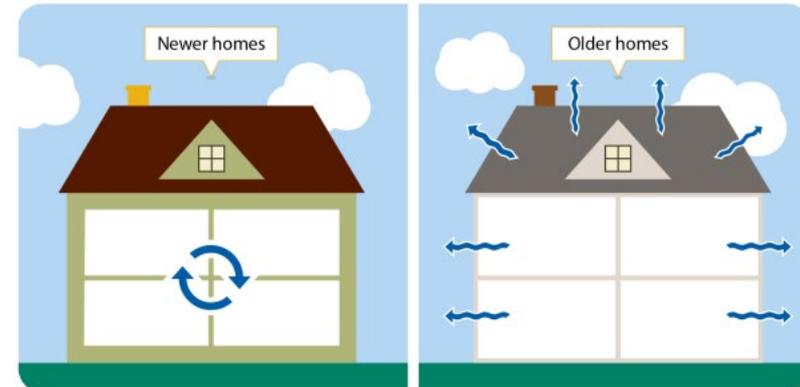
Cancer:

Any exposure increases risk of cancer.

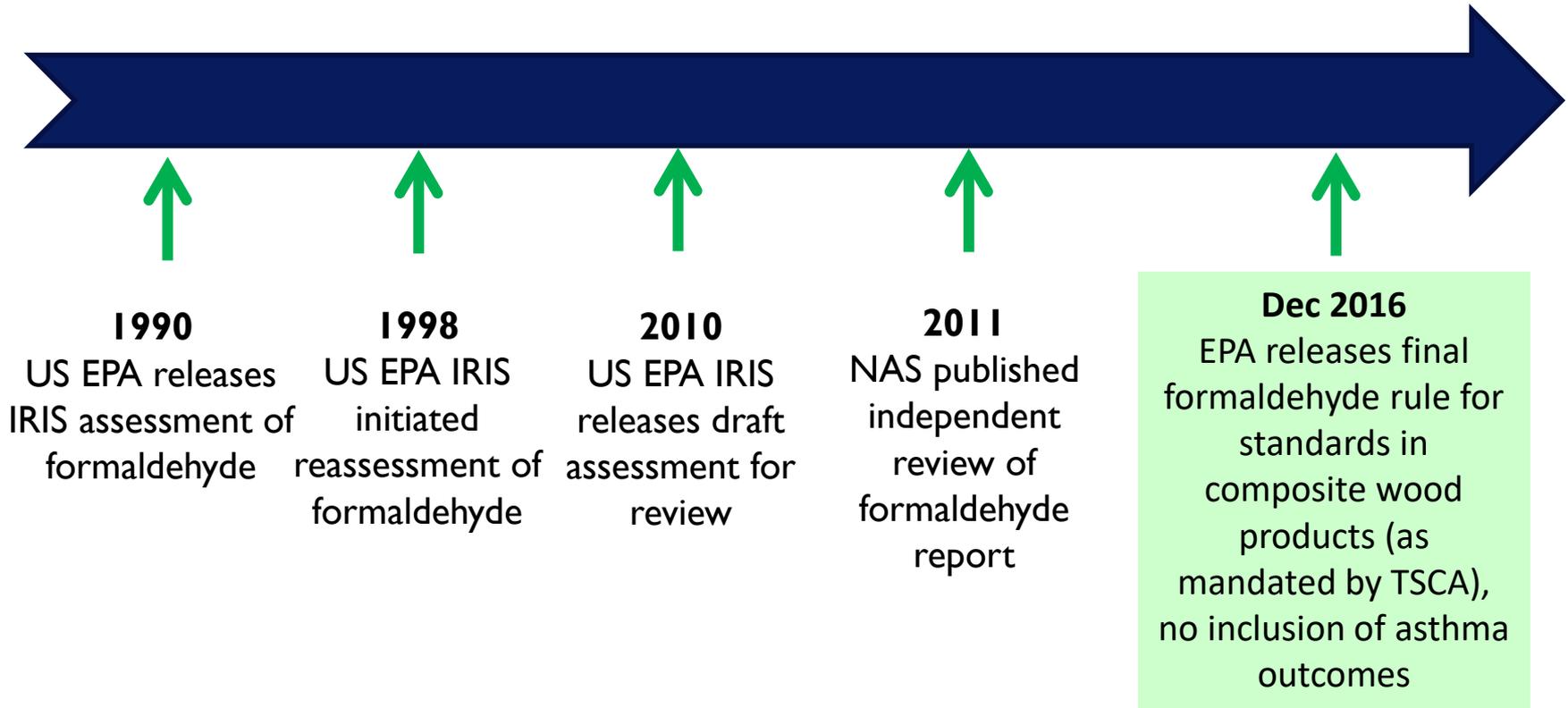
^{*}The assumption of a “safe level” is fundamentally flawed, as it does not sufficiently account for human variability and the many factors that make some people more susceptible than others.



Formaldehyde & Asthma Case Study: Why Formaldehyde?



Formaldehyde History



1990

US EPA releases IRIS assessment of formaldehyde

1998

US EPA IRIS initiated reassessment of formaldehyde

2010

US EPA IRIS releases draft assessment for review

2011

NAS published independent review of formaldehyde report

Dec 2016

EPA releases final formaldehyde rule for standards in composite wood products (as mandated by TSCA), no inclusion of asthma outcomes



EPA Benefits Valuation

Table ES-12-9: Total Annualized Costs, Benefits, and Net Benefits for All Options (millions 2010\$, 3 percent discount rate)

Analytical Option	Costs		Benefits		Net Benefits	
	Low End Estimate	High End Estimate	Lower Estimate	Higher Estimate	Lower Estimate	Higher Estimate
Option SE	\$100	\$100	\$162 18 +B	\$245 42 +B	\$62 (\$82) +B	\$145 (\$58) +B
Option SI	\$194 204	\$293	\$184 20 +B	\$278 48 +B	(\$109) 273 +B	\$84 (\$157) +B
Option SP	\$104	\$104	Not estimated	Not estimated	Not estimated	Not estimated
Option SN	\$143 128	\$185 137	\$192 21 +B	\$289 50 +B	\$7 (\$116) +B	\$146 (\$79) +B
Option SC	\$112	\$121	\$184 20 +B	\$278 48 +B	\$63 (\$101) +B	\$166 (\$64) +B
Option SCR	\$72	\$81	\$20 +B	\$48 +B	(\$61) +B	(\$24) +B
Option SEUR	\$60	\$60	\$18 +B	\$42 +B	(\$42) +B	(\$18) +B
Option SFCC	\$100	\$100	\$18 +B	\$42 +B	(\$82) +B	(\$58) +B
Option SCR SCUR (proposed)	\$72	\$81	\$184 20 +B	\$278 48 +B	\$103 (\$60) +B	\$206 (\$24) +B
Option CE	\$99	\$99	\$125 14 +B	\$188 32 +B	\$25 (\$86) +B	\$89 (\$67) +B
Option CI	\$192 203	\$292	\$142 16 +B	\$214 37 +B	(\$150) 277 +B	\$22 (\$167) +B
Option NE	\$379	\$379	\$639 76 +B	\$970 178 +B	\$259 (\$303) +B	\$591 (\$201) +B
Option NI	\$473 484	\$573	\$667 80 +B	\$1,013 186 +B	\$94 (\$493) +B	\$540 (\$297) +B

Option ~~SCR~~SCUR is the proposed option. Parentheses indicate negative net benefits.

Lower estimate of net benefits is calculated by subtracting high end cost estimate from lower benefits estimate.

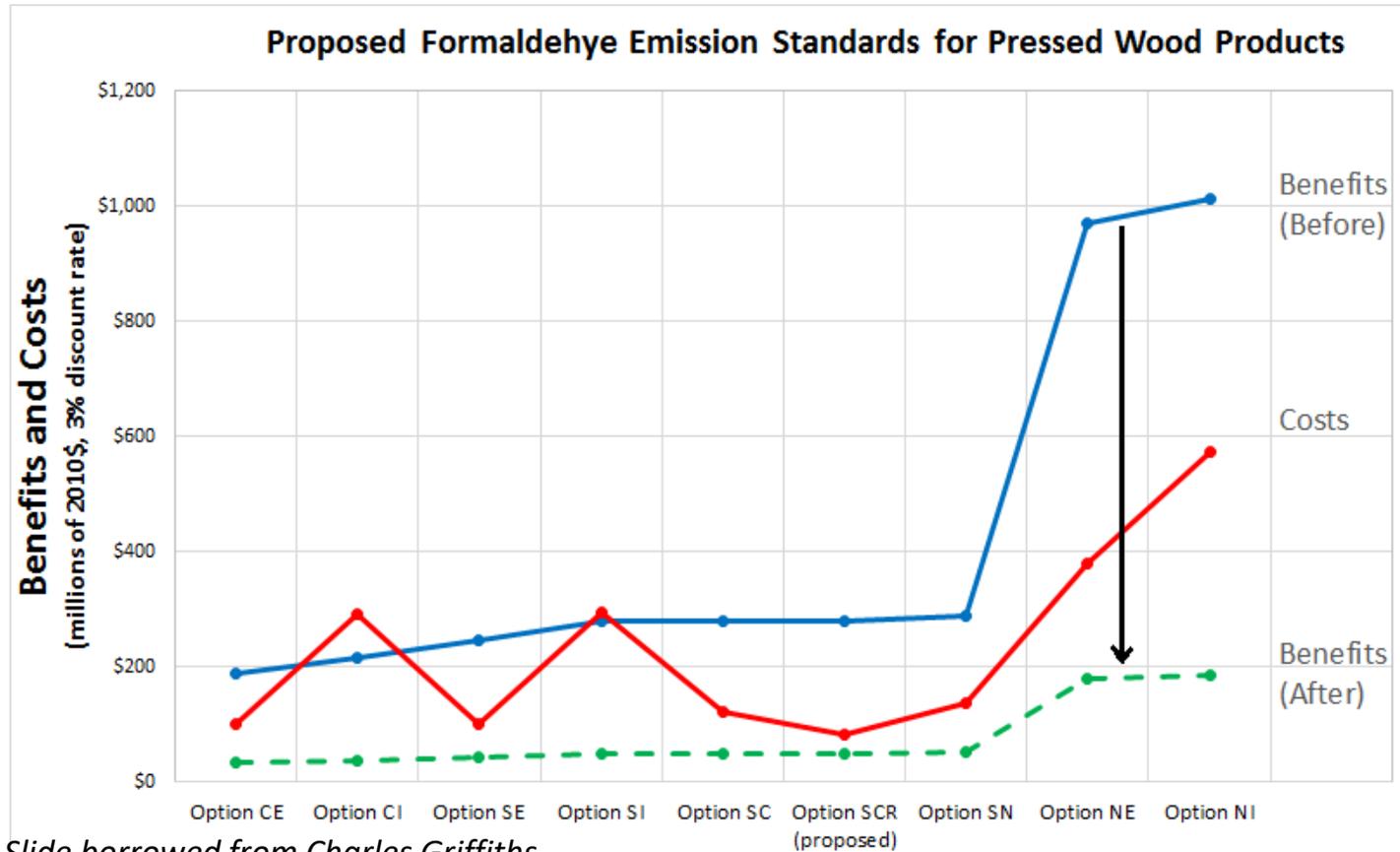
Higher estimate of net benefits is calculated by subtracting low end cost estimate from higher benefits estimate.

"B" represents the unquantified health benefits.

Slide borrowed from Charles Griffiths



EPA Benefits Valuation



Formaldehyde & Asthma Case Study

Review evidence of health benefits of preventing exposure to formaldehyde

- Systematic review of formaldehyde & asthma
- Produce concise, transparent and actionable conclusion
- Combine dose-response info with cost/incidence rates of asthma to monetize benefits of avoiding asthma
- Capture process of influencing change

→ Our case study illustrates how using robust methods of

→ Systematic review

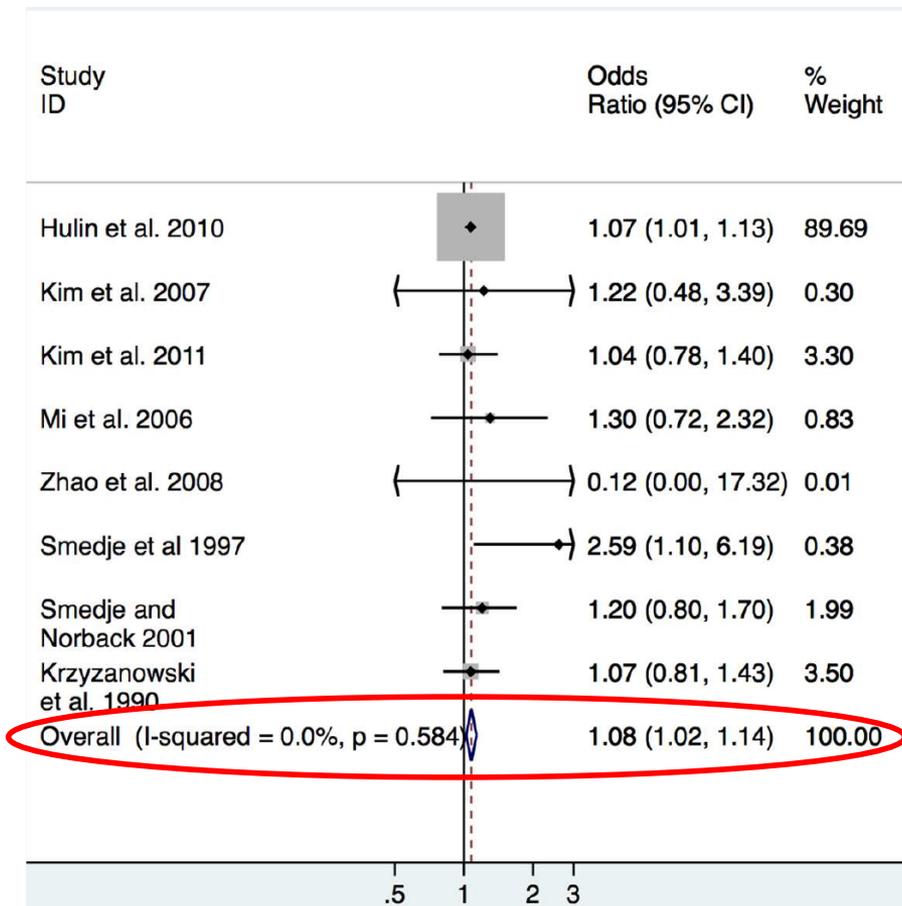
→ Dose response of noncancer endpoints

→ Benefits assessment down to zero

Can **improve use** of science in decision-making to better protect health



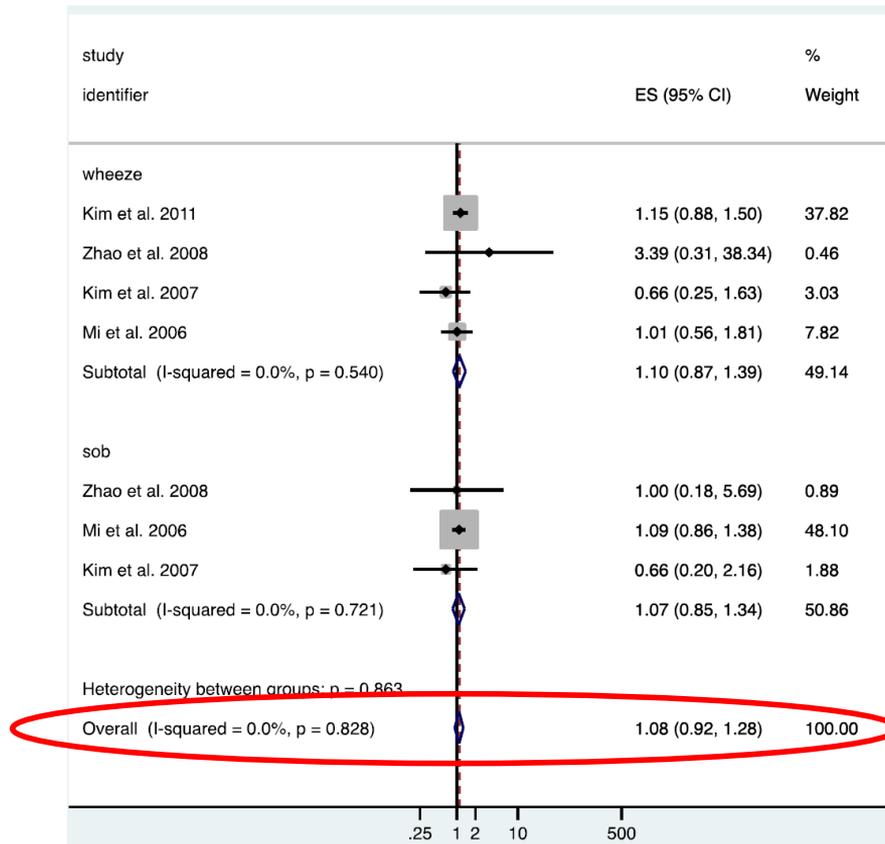
Meta-Analysis for Children Asthma Diagnosis



Indoor exposure to formaldehyde significantly associated with increased odds—8% increase per 10-fold exposure for children's asthma diagnosis



Meta-Analysis for Children Asthma Symptoms



Indoor exposure to formaldehyde showed increased odds—8% increase per 10-fold exposure for children's asthma symptoms in (wheeze, shortness of breath), but not statistically significant



Benefit-cost analysis

- Outcome: avoiding a case of asthma in children
- Full implementation of EPA's proposed rule on pressed wood products results in 2,805 fewer asthma cases annually
- Willingness to pay = \$75,024 annually



\$90 million across all children in the US over 30 years



Benefit-cost analysis

Proposed rule

~~\$184 – 278 million~~ **\$72 – 81 million**

OMB-modified rule

~~\$20 – 48 million~~ **\$72 – 81 million**

Lam et al. benefit estimates

\$210 million >> **\$72 – 81 million**

**Benefits outweigh
costs**



Lessons learned from formaldehyde

- Authors concluded there was “**sufficient**” evidence supporting associations between childhood and adult formaldehyde exposures with asthma diagnosis and symptoms
- Even with relatively “small” risks (8% increase), with ubiquitous exposures and chronic health outcomes the benefits can be significant
- Critical for policy decisions to **account for all relevant health outcomes to avoid underestimation of benefits**

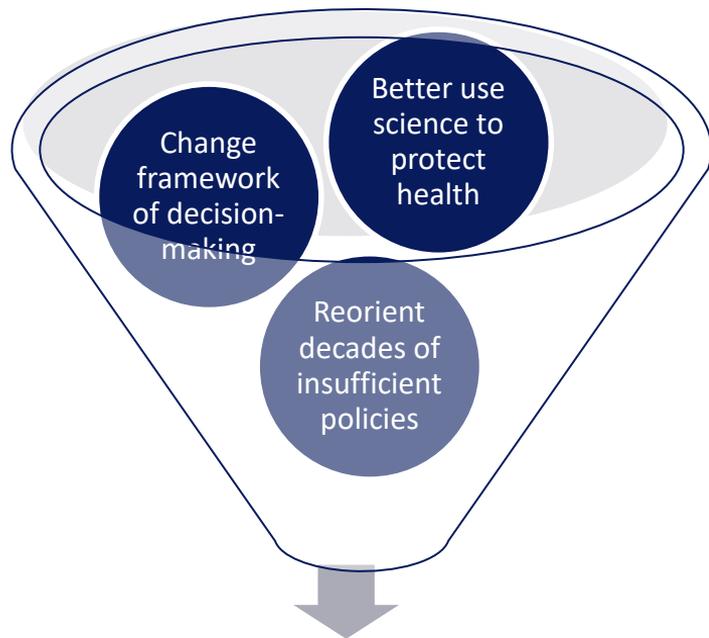


A Science-Based Agenda for Health-Protective Chemical Assessments and Decisions

- Strategic and specific scientific-based recommendations to improve key aspects of chemical hazard and risk assessment to support improved policy decisions that better protect public health



Our Consensus Principles



Concrete next step

- 1** Make industry pay for data collection 
- 2** Declare lack of data does not mean lack of risk 
- 3** Better identify and protect populations in harm's way 
- 4** Don't assume safety thresholds for population-wide exposures 
- 5** Account for conflicts of interest in risk assessments 



A Science-Based Agenda for Health-Protective Chemical Assessments and Decisions

Improve its inadequate approach to **exposure assessments** that have prevented the Agency from fully protecting communities



EPA thinks you hold it like this and that matters to you health.

EPA assumes when you shop, you touch 1 receipt a day with 3 fingers for 10 seconds.

A study of how people actually touch receipts found –

- Most people touch multiple receipts for 11+ minutes a day
- Many crumple it in their palms
- Some hold it in their mouths or use it as a napkin
- Others use it to blot grease on their pizza

So we're getting exposed to a lot more BPA* and other chemicals – than EPA acknowledges.

When evaluating harmful chemicals, EPA makes assumptions about how you are exposed.

For example, many shopping receipts have BPA, a chemical linked to:

- infertility
- heart disease
- cancer
- asthma

EPA is **underestimating risk** to health harms from many, many chemicals.

EPA can protect people better if its risk evaluations are based on real-world exposures.

#exposures UCSP Program on Reproductive Health and Environment

Update methods to consider **population variability** and increase protection for people burdened by environmental exposures and/or social stressors such as poverty and racism



How much will [any toxic chemical] harm you?

When EPA evaluates chemical risks, it assumes we're all similar.

But our differences can determine who is most at risk from toxic harms.

HOW MUCH you are exposed to

YOUR HEALTH pre-existing conditions, genetic makeup, pregnancy, or stage of development

WHERE YOU LIVE Old homes have lead paint. Urban areas have more smog. Polluting facilities contaminate neighbors.

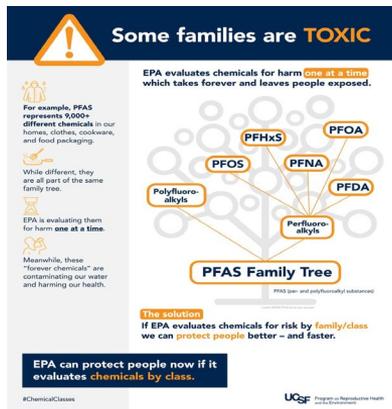
Just like pre-existing health conditions make people more susceptible to a virus, they also make people more susceptible to the harmful effects of a chemical.

The solution EPA's chemical risk evaluations must better consider variability and susceptibility to toxic harms.

EPA can protect people better by accounting for those most at risk.

#variability UCSP Program on Reproductive Health and Environment

Adopt a **class-based approach** to evaluate chemical risks rather than evaluating hazardous chemicals one at a time



Some families are TOXIC

EPA evaluates chemicals for harm **one at a time** which takes forever and leaves people exposed.

For example, PFAS represents 5000+ different chemicals in our homes, clothes, cookware, and food packaging.

While different, they are all part of the same family tree.

EPA is evaluating them for harm **one at a time**.

Meanwhile, these "forever chemicals" are contaminating our water and harming our health.

The solution If EPA evaluates chemicals for risk by **family/class** we can protect people better – and faster.

EPA can protect people now if it evaluates chemicals by class.

#ChemicalClasses UCSP Program on Reproductive Health and Environment

Quantify **non-cancer health outcomes** to better reflect real-world health consequences of exposures and improve benefit-cost analyses of regulations



EPA is failing to protect some people from harmful chemicals

EPA's approach to risk evaluation only protects some people.

assuming everyday exposures do no harm

disregarding how some people are vulnerable to conditions like infertility or Parkinson's disease

failing to consider impacts on people who are exposed to high levels or multiple pollutants

The solution EPA can protect more people from harmful chemicals by using updated methods* that more realistically estimate real-world risk and harm.

EPA needs to protect ALL of us from harmful chemicals.

#habilitateMethods UCSP Program on Reproductive Health and Environment



Recommendations

Regulators should:

1. Incorporate probabilistic dose-response methods into risk assessments
2. Quantify non-cancer health risks across the range of exposure levels
3. Consider severity of health effect and how many people are affected when selecting acceptable exposure levels

EPA needs a bigger umbrella

The problem EPA's approach to risk evaluation leaves many people unprotected from harmful chemicals

The solution EPA can protect more people by using updated methods* that more realistically estimate real-world risk and harm.

EPA needs more inclusive methods to protect people better from harmful chemicals.

*Probabilistic methods in chemical risk evaluations

EPA's chemical risk evaluations leave many people unprotected by:

- assuming everyday exposures do no harm
- failing to account for underlying conditions like infertility and Parkinson's
- failing to consider people exposed to multiple pollutants

UCSF Program on Reproductive Health and the Environment

Science Action Network FOR HEALTH AND THE ENVIRONMENT



President Biden's Regulatory Review Memo

“take into account the distributional consequences of regulations...to ensure that regulatory initiatives appropriately benefit and do not inappropriately burden disadvantaged, vulnerable, or marginalized communities”.

U.S. Executive Office of the President. *Presidential Memorandum, Modernizing Regulatory Review*, § 2(b)(i) , **2021**



How Can You Engage?

- Regular meetings with EPA
- Risk Evaluation - Engaging with comments process and ensuring EPA applies these methods
- Risk Management – Engaging in the consultations and commenting on chemical management as it relates to your jurisdiction



Program on Reproductive Health and the Environment

Science | Policy | Education | Communications

YOU'RE INVITED

Greetings,

We are inviting you to join us on Capitol Hill in Washington, DC, **Wednesday, March 29, at 1 PM ET** for a legislative briefing where we will discuss how the U.S. Environmental Protection Agency (EPA) can use the best available science to better protect people and highly impacted communities from harmful chemicals.

Due to security at the Capitol Building, you must be registered to attend.

Register here: bit.ly/chb2023



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