

Recent U.S. EPA Initiatives on Chemical Testing and Assessment: Where's the Beef?

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finding the ways that work

What I'll cover

- Bkgrd: Efforts leading to ChAMP*
- Elements of ChAMP (underway, proposed)
- Limitations and problems
- Why ChAMP just doesn't have the REACH (or the CA-CMP)

* EPA's new Chemical Assessment and Management Program

Toxic Substances Control Act Theory ...

TSCA Data Availability Policy (1976):

“It is the policy of the United States that ... **adequate data** should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the **responsibility of those who manufacture [such] chemicals.**”

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.... and Practice

National Academy of Sciences, *Toxicity Testing* (1984)

- 78% of high-volume chemicals lacked even “minimal toxicity information”
- Environmental Defense, *Toxic Ignorance* (1997)
 - 71% of HPV sample: basic SIDS* mammalian tox dataset not publicly available
- US EPA (1998)
 - 93% of ~3000 HPV chemicals lacked publicly available SIDS data set (all elements)
 - 43% had *no* publicly available SIDS data
- Chemical Manufacturers Association (1998)
 - 91% of HPV chemicals lacked public SIDS

* Screening Information Data Set

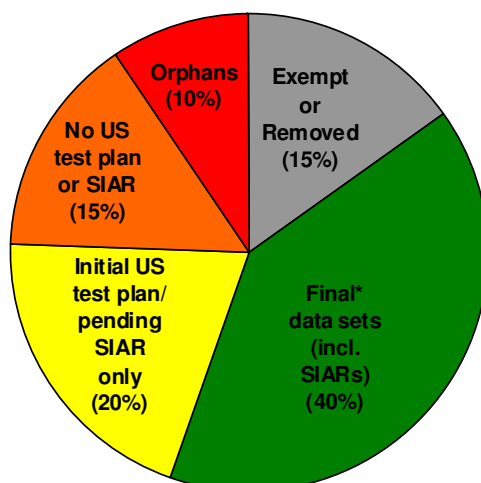
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HPV Challenge Program Framework

- Manufacturers to voluntarily “sponsor” HPV chemicals: identify, fill SIDS gaps
- Two routes deemed acceptable by EPA:
 - Through US program directly
 - Through parallel ICCA / OECD SIDS Program
- Work was to be completed by 2004, data made public by end of 2005

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Overall Status of the 2,782 HPV Challenge Core List Chemicals
as of July 6, 2007



* Most final US datasets not yet reviewed for quality or completeness

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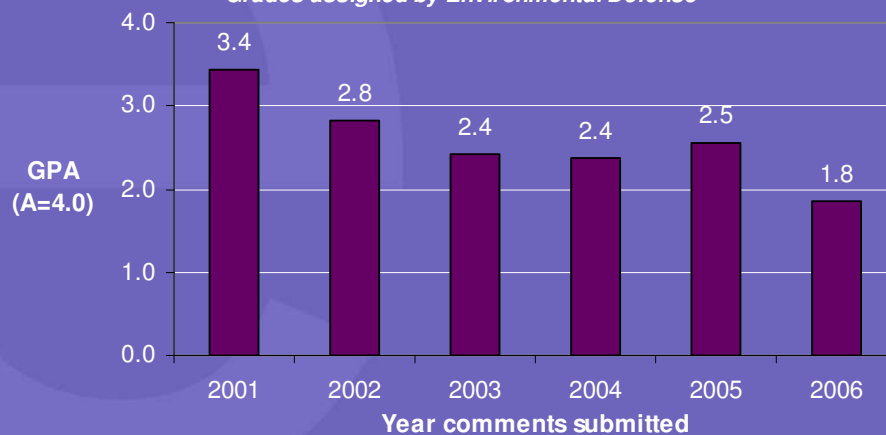
HPV Challenge Status

- 3 years after final data sets were due, only about half have been submitted.
- 10% (267) of eligible HPVs are orphans (not sponsored); EPA has issued test rule for only 16, took 5 years.
- The grade point average for initial industry submissions sank from a solid B-plus in 2001 to a C-minus in 2006.

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Test Plan "Fatigue"?

HPV Test Plan Grade Point Average, by Year
Grades assigned by Environmental Defense



Source: ED HPV Tracker, 11-30-06

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Still to come?

- 574 “emerged” HPVs
 - Reached HPV level since Challenge launch
 - EPA public data availability study on 235:
 - 52% had NO hazard data (compared to 43% in 1st HPV study)
 - 2% of them had full screening data set (compared to 7% in 1st study)
 - Only 231 sponsored via industry Extended HPV Program, 15 data submissions

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Success? Jury is still out

- Challenge is still far from finished
- Data quality, completeness a big unknown; data gaps in “final” datasets
- How will data be assessed and used?
- EPA resources insufficient, declining
- Industry not making hazard data development an “evergreen” practice

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Next Steps for HPVs

- EPA asked NPPTAC to advise on next steps – final recommendation Feb 2005:
 - evaluate quality and completeness of each data set and determine adequacy
 - determine level of hazard for each SIDS endpoint
 - develop and make public a hazard characterization of each substance
- EPA agreed to complete by 2010

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HPV Hazard Characterizations

Current status

- ~90 HCs posted covering 250 chemicals
- For 30%, data gaps in final submissions
- For human health endpoints
 - ~1/4 ranked high hazard
 - ~1/2 ranked moderate hazard
 - ~1/4 ranked low hazard

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Meanwhile, use and exposure data in the works

- TSCA Inventory Update Rule (IUR) requires periodic mfctr reporting
- 1986-1990-1994-1998-2002
 - Production location, volume range data only
 - $\geq 10,000$ lbs/yr/site threshold
- 2006-2011-2016, etc.
 - Some downstream processing, use, exposure data
 - $\geq 25,000$ lbs/yr/site threshold

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IUR use and exposure data

For all reported chemicals (~6,750) –
“reasonably ascertainable” data on:

- # workers reasonably likely to be exposed;
- physical form(s) of the chemical substance; and
- maximum concentration of the chemical substance as it leaves the submitter's possession.

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IUR use and exposure data

For HPV chemicals only (~2,750) –
“readily obtainable” data on:

- industrial functions (e.g., adhesive, solvent)
- #, types of downstream processing and commercial-use sites
- # workers handling chemical at each site
- product types (e.g., paints)
- maximum concentration in each product
- whether products intended for use by children

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Enter ChAMP

- Arose from US-Canada-Mexico Security and Prosperity Partnership (SPP), 8/07
- US commitment under SPP:
 - By 2012, assess and initiate needed action on existing chemicals produced $\geq 25,000$ lbs/yr in the US

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What is ChAMP?

1. For ~2,750 organic HPV chemicals
 - EPA to use Challenge and IUR data to develop “risk-based prioritizations” (RBP)
 - Assign H/M/L risk concern for workers, children, general population, consumers, aquatic environment
 - Supported by hazard/env. fate/exposure characterization documents

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What is ChAMP?

2. For ~750 inorganic chemicals reported for 1st time in 2006, no use/exp data
 - EPA proposes another voluntary Challenge for inorganic HPVs (~450)
3. For ~4,000 organic MPV* chemicals
 - EPA to conduct hazard screening (à la Canada)
 - Will rely on existing data, modeling

* Moderate production volume: 25,000 – 1 million lbs/yr

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Can ChAMP deliver on HPVs?

- Requires screening-level hazard and use/exposure data for ~2,750 HPVs
- Hazard data missing for:
 - orphans: only test rule covers 16 of 267
 - 100s of Challenge HPVs (not yet done)
 - gaps in “final” Challenge datasets (30%?)
 - >550 Extended HPV Program chemicals

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Can ChAMP deliver on HPVs?

- Use/exposure data mostly from IUR
- IUR data not yet public, but EPA using it
 - Basis for exposure part of EPA’s 1st 8 RBPs
- How much claimed CBI? (likely most)
- How much not submitted because not “readily obtainable” (NRO)?
 - 5 of the 8 RBPs indicate some data NRO (but EPA usually does not specify what)

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Can ChAMP deliver on HPVs?

- Utter lack of transparency re IUR data
- For each chemical, EPA needs to:
 - List all IUR use/exposure elements
 - For each, indicate whether data were:
 - submitted and claimed CBI
 - submitted, not claimed CBI (make public)
 - not submitted because claimed NRO

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Can ChAMP deliver on HPVs?

- Bad risk decisions worse than none!
Two examples from EPA RBPs:
 1. Chems used in paint strippers, polishes
 - Low risk to kids since IUR data do not indicate use in products intended for kids (<14 y.o.)
 2. Chems found to be severe eye irritants with high worker exposure potential
 - Low risk to workers – EPA assumes PPE used, effective, even though worker exposure data not submitted, claimed NRO

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Can ChAMP deliver on HPVs?

- EPA proposes little action even for high-risk chemicals
 - 3 of 8 RBPs identify high risk concerns: high hazard and high exposure potential
 - EPA's action: "encourage companies to provide available information on a voluntary and non-confidential basis" to confirm or refute the finding
 - Info could lead to more testing or adding chemical to voluntary assessment program

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Inorganic HPVs: Another voluntary Challenge

Voluntary program track record not good:

- HPV Challenge fell well short of goals
- Extended HPV Program much worse: 40% sponsorship, <3% submissions
- VCCEP* is down for the count
 - Industry develops data and assessment
 - 20 chemicals, goal to identify data needs

* Voluntary Children's Chemical Evaluation Program

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Hazard screening for MPVs

- Apply to 4,000 MPV chemicals
- Idea proposed by NGOs on NPPTAC in 2005
 - Opposed at the time by both industry, EPA
 - What changed? REACH was adopted, Canada screened 23,000 chemicals
- Use Canada data, estimation modeling, other tools EPA uses for new chemicals

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Hazard screening for MPVs

- Reasonable, given TSCA's high bar to require data
- But available data very limited – Canada identified 1000s of chems with insufficient or only low-quality data
- Which is better approach?
 - prioritize using incomplete existing info
 - develop good data, then prioritize (REACH)

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Proposed new initiatives

- Reset the TSCA Inventory
- Publish list of chemicals that “may present an unreasonable risk”

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Resetting the TSCA Inventory

- Currently 83,000 chemicals (15,000 CBI)
 - Includes 28,000 polymers
 - 62,000 were in commerce ca. 1979
 - 21,000 new chemicals added since
- EPA IUR data indicates HPV + MPV =
 - ~7,500 in commerce in 2005 (≥ 25 K lbs/yr)
 - ~15,500 in commerce 1985-2001 (≥ 10 K lbs/yr)
 - Excludes 1000s of polymers (not reportable)
- How many LPVs in commerce? Likely even more

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Resetting the TSCA Inventory

If done, EPA must:

- Require reporting over 5-10 year window
- Apply no lower threshold, no exemptions
- Retain list of any “removed” chemicals
- Subject removed chemicals to new chemical notification and review if they return to commerce

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Establishing a “Risk List”

- Under TSCA §5(b)(4), EPA can make list of chemicals that “present or may present an unreasonable risk”
- Never before used, would require full notice-and-comment rulemaking
- If EPA also issued SNUR* (separate rule), notifier would have burden to show new use “will not present an unreasonable risk”

* Significant New Use Rule

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Establishing a “Risk List”

- Idea has merit: Equivalent to REACH candidate list for Authorization?
- Clear criteria needed up front, developed through transparent, public process
- Identify listing criteria for hazard, use and/or exposure

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Is ChAMP competitive?

- EPA, industry say ChAMP is US answer to REACH, Canada initiatives
- ChAMP's limits are same as TSCA's
 - High bar to require testing:
 - Rely on existing data no matter how poor
 - Propose more voluntary programs
 - Unable to get reliable use and exposure data:
 - Use what it can get, and obscure how incomplete
 - Insurmountable bar to regulate chemicals:
 - Encourage companies to provide more data

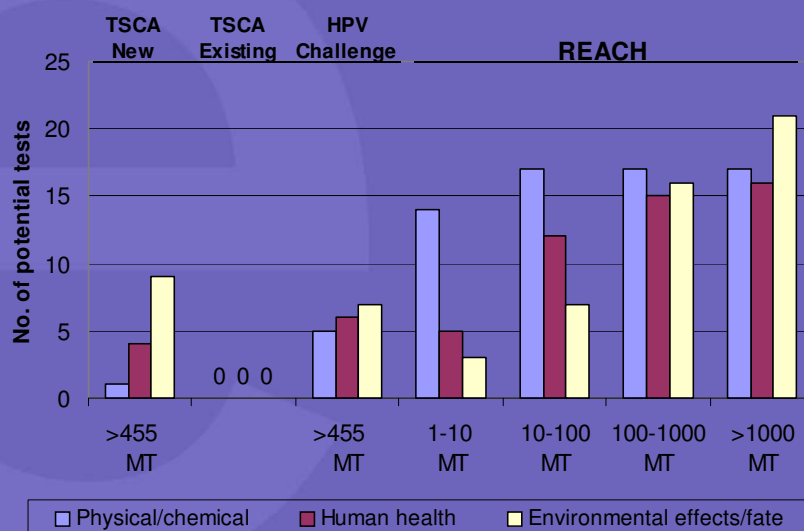
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Is ChAMP competitive?

	ChAMP-TSCA	CA-CEPA	REACH
# chems targeted	7,500	23,000	30,000
Means to get hazard data	Use existing data, voluntary efforts, case-by-case rulemaking	Use existing, less onerous case-by-case rulemaking	Mandatory: no data, no market
Use/exposure data	Manufacturers, HPVs only (loophole); case-by-case rulemaking	Means under development	Reaches downstream users as well as manufacturers
Amount of hazard data	See chart		

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Number of potential tests under TSCA and REACH



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Is ChAMP competitive?

	ChAMP-TSCA	CA-CEPA	REACH
CBI	Wide allowance for claims		Specific rules
Updating of info	Infrequent, exemptions, high threshold	Means under development	Automatic whenever sign. change
Identifying chemicals of concern	No clear criteria, case-by-case	CEPA specified hazard, exposure criteria	Clear hazard, exposure criteria
Follow-up action	Encourage companies to submit data	Rebuttable presumption of regulation	Subject to Evaluation, Authorization
Burden of proof to regulate	On govt to prove unreasonable risk	On govt to prove potential harm (less onerous)	On industry to prove safety

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Thank you!

Slides and analysis at

www.edf.org/page.cfm?tagID=41

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Key structural constraints in US chemicals policy

Information development:

- Limited tracking of chemicals in commerce
- Upfront data not required for new chemicals
- High hurdle to require chemical testing
- Reliance on “old” toxicology

Information sharing:

- Overly broad allowances for CBI claims
- Few requirements to make information public

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Key structural constraints in US chemicals policy

Acting on Information:

- Virtually no criteria to identify chemicals warranting further action; case-by-case
- No mandate to assess existing chemicals
- Only a single, time- and data-constrained assessment opportunity for new chemicals
- Near-impossible hurdle to regulate existing chemicals

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TSCA

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