Is ChAMP a Winning Strategy?

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Three Main Questions

- What is ChAMP achieving?
- Is the process of evaluating chemicals under ChAMP fundamentally sound?
- What are potential improvements to ChAMP?

ChAMP Risk-Based Prioritizations

- Hazard Characterization
- Exposure Characterization
- Integrated Screening-Level Risk Characterization
- Risk Based Prioritizations

Risk Based Prioritization Process

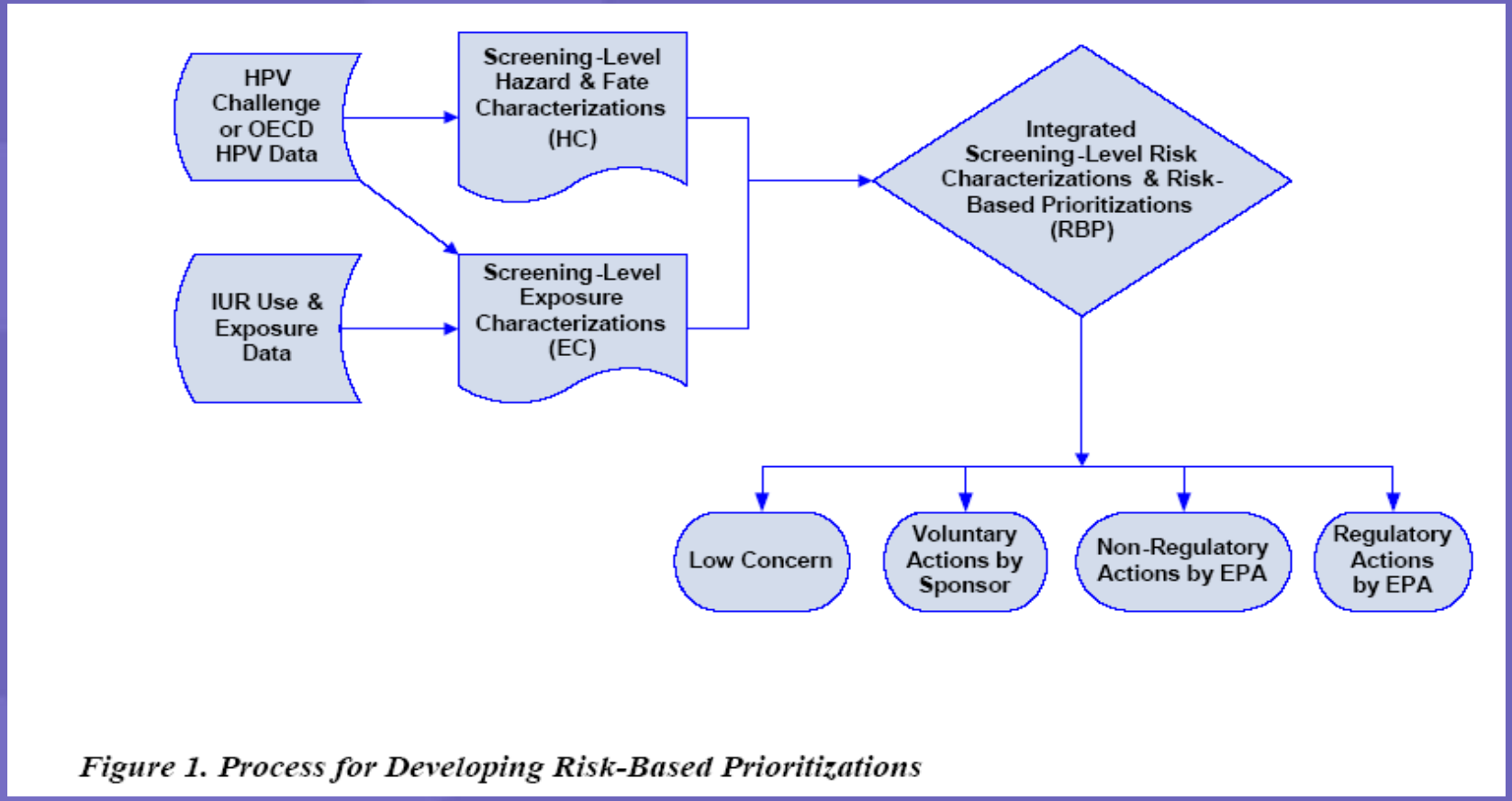

Figure 1. Process for Developing Risk-Based Prioritizations

Hazard Characterizations

- Physical/Chemical Properties, Environmental Fate Parameters
- Aquatic Toxicity
- Human Health Toxicity (SIDS Endpoints):
  - Acute
  - Repeated Dose (systemic)
  - Reproductive
  - Developmental
  - Genetic Toxicity
  - Irritation (skin or eye)
  - Carcinogenicity
  - Neurotoxicity
  - Immunotoxicity

United Nations Globally Harmonized System of Classification and Labeling (GHS) criteria

- Classification of chemicals by types of hazard
- Harmonized hazard communication elements, including labels and safety data sheets
- Modified GHS criteria used by OPPT
- http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html

Chemical Properties & Environmental Fate Criteria

PHYSICAL/CHEMICAL PROPERTY CHARACTERIZATION CRITERIA		
Parameter	Characterization	Value Range
Vapor pressure (mm Hg)	Negligible	$< 10^{-8}$
	Low	$\geq 10^{-8}$ up to 10^{-4}
	Moderate	$\geq 10^{-4}$ up to 1
	High	≥ 1
Water solubility (mg/L)	Negligible	$< 10^{-3}$
	Low	$\geq 10^{-3}$ up to 1
	Moderate	≥ 1 up to 1000
	High	≥ 1000

ENVIRONMENTAL FATE CHARACTERIZATION CRITERIA		
Parameter	Characterization	Value Range
Mobility (K_{oc} L/kg)	High Mobility	< 2
	Moderate Mobility	2 to 4
	Low Mobility	> 4
Volatility Henry's Law Constant (atm m^3/mol)	High	$> 10^{-3}$
	Moderate	10^{-3} to 10^{-7}
	Low	$< 10^{-7}$
Hydrolysis (Half-life)	Rapid	< 2 hours
	Moderate	$\geq$ 2 hours to 2 days
	Slow	$\geq$ 2 days to 20 days
	Negligible	> 20 days
Photodegradation (Half-life)	Rapid	< 2 hours
	Moderate	$\geq$ 2 hours to 1 day
	Slow	$\geq$ 1 day to 10 days
	Negligible	> 10 days
Ready Biodegradation (within 28 days)	Readily Biodegradable	$\geq$ 70% DOC removal (OECD 301 A and OECD 301 E); $\geq$60% theoretical carbon dioxide (ThCO2) (OECD 301 B); $\geq$60% theoretical oxygen demand (ThOD) (OECD 301 C, OECD 301 D and OECD 301 F).
	Not Readily Biodegradable	If results fall below the criteria above
Environmental Biodegradation (Environmental Half-life)	Rapid	< 2 days
	Moderate	$\geq$2 days to 2 months
	Slow to negligible	> 2 months

http://www.epa.gov/champ/

ChAMP Critique

Persistence and Bioaccumulation Criteria

PERSISTENCE CHARACTERIZATION CRITERIA			
Environmental Medium	Hazard Characterization		
	Not Persistent	Persistent	
Water, Soil, Sediment*	Low ("P1")	Moderate ("P2")	High ("P3")
	< 60 Days	60 - 180 days	> 180 Days
* For comparison purposes, calculations are based on 30 days in a month.			

BIOACCUMULATION CHARACTERIZATION CRITERIA			
	Hazard Characterization		
	Not Bioaccumulative	Bioaccumulative	
	Low ("B1")	Moderate ("B2")	High ("B3")
Bioaccumulation Factor (BAF)	< 1000	1000 - 5000	> 5000
Bioconcentration Factor (BCF)	< 1000	1000 - 5000	> 5000

http://www.epa.gov/champ/

ChAMP Critique

Criteria Aquatic Toxicity

AQUATIC TOXICITY CHARACTERIZATION CRITERIA			
Endpoint	Hazard Characterization		
	High	Moderate	Low
Acute LC_{50} or EC_{50} (mg/L)	$\leq$ 1	> 1 – 10	> 10
Chronic (ChV or LOEC) (mg/L)	$\leq$ 0.1	> 0.1 - 10	> 10

- Fish, Invertebrates, Aquatic Plants
- http://www.epa.gov/champ/

Repeated Dose Toxicity Criteria

REPEATED-DOSE/SYSTEMIC TOXICITY CHARACTERIZATION CRITERIA*			
Route of Administration (units)	Hazard Characterization		
	High	Moderate	Low
Oral (mg/kg-bw/day)			
90-day (13 weeks)	<10	10 – 100	>100
40-50 days	< 20	20 – 200	> 200
28-days (4 weeks)	<30	30 – 300	> 300
Dermal (mg/kg-bw/day)			
90-day (13 weeks)	<20	20 – 200	>200
40-50 days	<40	40 – 400	>400
28-days (4 weeks)	<60	60 – 600	>600
Inhalation(vapor) (mg/L/6hrs/day)			
90-day (13 weeks)	<0.2	0.2 – 1.0	>1.0
40-50 days	<0.4	0.4 – 2.0	>2.0
28-days (4 weeks)	<0.6	0.6 – 3.0	>3.0
Inhalation(dust/mist/fume) (mg/L/6hrs/day)	<0.02	0.02 – 0.2	>0.2
90-day (13 weeks)	<0.04	0.04 – 0.4	>0.4
40-50 days	<0.06	0.06 – 0.6	>0.6
28-days (4 weeks)			
Inhalation(gas) (ppm/6hrs/day)			
90-day (13 weeks)	<50	50 - 250	>250
40-50 days	<100	100 - 500	>500
28-days (4 weeks)	<150	300 - 750	>750

* All values are LOAELs. The 90-day values (i.e., first line in each row) are from the GHS scheme. The other values are pro-rated estimates OPPT has calculated to accommodate the various data submitted under the HPV Challenge Program. This method is also suggested for use by the GHS program (see Section 3.9.2.5 in http://www.unece.org/trans/danger/publi/ghs/ghs_rev02/English/03e_part3.pdf

- Specific to route of administration and duration of dosing

http://www.epa.gov/champ/

Reproductive/Developmental Toxicity Criteria

REPRODUCTIVE/DEVELOPMENTAL TOXICITY CHARACTERIZATION CRITERIA*			
Route of Administration (units)	Hazard Characterization		
	High	Moderate	Low
Oral (mg/kg-bw/day)	<50	50 – 250	>250
Dermal (mg/kg-bw/day)	<100	100 – 500	>500
Inhalation(vapor) (mg/L/day)	<1.0	1 – 2.5	>2.5
Inhalation (dust/mist/fume) (mg/L/day)	<0.1	0.1 – 0.5	>0.5
Inhalation (gas) (ppm/day)	<50	50 - 250	>250
* All values are LOAELs. The oral values are taken directly from the OPPT criteria for reviewing TSCA 8(e) submissions mentioned in the text. The other values are pro-rated estimates OPPT has calculated to accommodate the various data submitted under the HPV Challenge Program. The estimates are based on the routes of administration differences noted above in the repeated-dose criteria table in Section 3.2.			

- Modification of GHS criteria that does not specify thresholds.
- Used by OPPTS, but derivation not made public

http://www.epa.gov/champ/

ChAMP Critique

Receptor-Based Exposure & Risk Characterizations

- General Public - from releases to environment
- Workers
- Consumers – also commercial workers
- Children – child specific uses or incidental household exposures

Exposure Characterization

- Qualitative and based largely on surrogates for exposure, including use and exposure-related information.
- Hampered by CBI and NRI claims.
- Absence of mechanisms to collect pertinent information throughout value chain.

Risk-Based Prioritization Process

- The RBP begins with the information on a chemical provided in the hazard, exposure, and risk characterizations, taking into consideration the existing regulations and other ongoing activities.
- Focus is on what is needed for regulatory purposes under TSCA.

Prioritization

- "In determining whether a chemical or category is a high, medium, or low priority for further assessment or risk management activities, OPPT begins with the risk characterization and incorporates policy and regulatory considerations. Chemicals are prioritized in order to identify which chemicals present the greatest potential need for additional evaluation or other follow-up action."

Results: First 220 Chemicals

Hazard Characterization Ranking

Hazard Rank	Number of Chemicals
High	34
Medium	66
Low	112
Total	212**

- Twenty high hazard chemicals from one category (aluminum alkyls)
- Four chemicals are also high exposure, risk, priority
- **Data not submitted for 8 chemicals

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

Risk Characterization Approach EPA vs EDF

Decision Matrix for Risk Characterization

HAZARD	EXPOSURE: Low	EXPOSURE: Medium	EXPOSURE: High
Low	L	L	L
Moderate	L	M	M
High	L	M	H

- Given significant uncertainty regarding exposure information:
- Consider high hazard + medium exposure or moderate hazard + high exposure = high risk
- Consider high hazard + low exposure or low hazard + high exposure = moderate risk

Risk Characterization Results

Exposure Rank	General Population	Workers	Consumers	Children
High	4	9	5	4
Moderate	42	36	40	24
Low	166	167	167	184
Total	212**	212**	212**	212**

- **Data not submitted for 8 chemicals

Prioritization Results

Risk-Based Prioritization (RBP) Decisions Summary

Total RBP Chemicals	High	Medium	Low
220	14	56	150

- Of 14 high priority chemicals:
  - 8 have no data
  - 4 are both high hazard & high exposure
  - 1 is high eco hazard, high exposure
  - 1 is medium hazard, high eco hazard, high exposure

High Priority Chemicals

- 541-73-11,3- Dichlorobenzene
- 110-71-4 Ethane, 1,2-dimethoxy- (monoglyme)
- 111-96-6 (bis(2-methoxyethyl)ether (Diglyme)
- 7439-97-6 Mercury
- 3194-55-6 1,2,5,6,9,10 hexabromocyclododecane
- 101-20-2 Triclocarban
- Compare with:
  - EU identified 15 substances in initial round of evaluation
  - ChemSec (NGO) identified 220 substances

Follow-Up Action High Priority

- *High Priority*: Information available to EPA on chemicals assigned to this priority suggests that these chemicals appear to have more serious potential risk concerns.
- EPA will determine whether there is a need for risk management actions, regulations, and/or more comprehensive data.
- EPA will encourage prompt voluntary actions to better understand or mitigate potential risks for high-priority chemicals and will also identify the need to act directly via regulatory means.

Follow-up Action Med Priority

- *Medium Priority*: Information available to EPA on chemicals assigned to this priority suggests possible concerns, but with risk issues or uncertainties that might be resolved if additional data (e.g., on exposures, controls, and/or hazards) were available to provide a basis for evaluating the potential concerns.
- EPA will encourage voluntary actions to better understand or mitigate potential risks for medium priority chemicals and may identify the need to act directly via regulatory means.

Problems with Hazard Ranking

- Some endpoints ignored or dismissed
- Improper characterization using GHS criteria
- No explicit consideration of vulnerability of children

Problems with Exposure Characterization

- Based on (virtually) no data

"With rare exceptions, the IUR data set, HPV Challenge Program submissions, and other public information available to OPPT for this prioritization exercise do not include data that would allow the quantitative characterization of the magnitude, frequency, duration, or route of exposure for any potentially exposed population. Most of the available information consists only of general chemical manufacturing, importation, processing, and broad category-of-use information."

page 13, Methods doc

Calls for Precautionary Approach

- Screening level characterizations.
- Inadequate exposure information.
- Err on the side of inclusion not exclusion.
- Subsequent evaluations can correct for over-inclusion more readily than over-exclusion.

Valuable Information Lost

- Opportunities to harmonize hazard information
- Hazard information is critical to informed decision-making
- Risk characterizations are NOT POSSIBLE without reliable hazard & exposure data
- Prioritization needs depend on users of information

Beyond TSCA

- Risk focus limits the discussion to TSCA.
- Opportunities beyond TSCA regarding green chemistry and sustainability initiatives.

ChAMP Opportunities

- Advancing green chemistry agenda
- Evaluation of alternative test methods
- Integration of new science, emerging endpoints of interest

Green Chemistry Opportunities

- Based on how chemicals are used (functional classes)
- Compare chemicals within same functional use
- Comparison of hazard rankings
- Comparison of traditional tox tests with alternative tox tests

Greater Opportunities to Explore Meaning of Alternative Tests

Table 1 - DfE Screen for Solvents (Phase I)

Phase I Solvent Classes	Alcohols
	Esters
	Ethylene Glycol Ethers (EGEs)
	Propylene Glycol Ethers (PGEs)
Attributes of Concern for Phase I Solvents	Carcinogenicity
	Neurotoxicity
	Acute Mammalian Toxicity
	Reproductive and Developmental Toxicity
	Repeated-Dose Toxicity
	Environmental Fate and Toxicity

- Set of chemicals in same functional class
- Set of data for each chemical
- Add data from alternative test methods

Clean Production Action Green Screen Flame Retardants

http://www.cleanproduction.org/Greenscreen.php

TABLE 5: **Hazard Profiles of Phosphorous-based and DecaBDE Flame Retardants (and their breakdown products)**

Chemical	Chemical Abstract Servies Registry Number (CAS#)	% in Formulation	Human Health Effects: Priority Effects: Carcinogenic	Mutagenic	Reproductive	Developmental	Endocrine Disruption	Neurological	Acute Toxicity	Systemic/Organ Effects	Sensitization (skin)	Sensitization (respiratory)	Irritation/Corrosion (skin)	Irritation/Corrosion (eyes)	Immune System Effects	Ecotox.: Acute	Chronic	Fate: Persistence	Bioaccumulation	Breakdown Products: Metabolites	Degradation Products
Bisphenol A diphosphate (BPADP/BAPP) - CAS# 181028-79-5																					
Phosphoric acid, (1-methylethylidene) di-4, 1-phenylene tetraphenyl ester	5945-33-5	~85	*L*	*L*	*L*	*L*	nd	*L*	*L*	*M*	*L*	nd	*L*	*M*	*L*	*L*	*L*	*H*	*L*	nd	phenol + bisphenol A
Phosphoric acid, bis[4-[1-[4-[(diphenoxyphos-phinyl)oxy]phenyl]-1-methylethyl]phenyl] phenyl ester	83029-72-5	~11	*L*	*L*	*L*	*L*	nd	*L*	*L*	*M*	*L*	nd	*L*	*M*	*L*	*L*	*L*	*vH*	*L*	nd	phenol + bisphenol A
Triphenyl Phosphate	115-86-6	<3	*L*	L	L	L	nd	L	L	M	L	nd	L	M	L	H	*H*	L	M	nd	diphenyl phosphate + phenol
Breakdown Products																					
Bisphenol A: contaminant and degradation product	80-05-7		L	L	M	M	H	nd	L	M	M	M	L	H	M	M	M	L	L		
Phenol: contaminant and degradation product	108-95-2		L	M	L	L	L	M	M	H	L	L	H	H	M	M	M	L	L		
Diphenyl phosphate	838-85-7		*Insufficient data for evaluation*																		
Resorcinol bis(diphenylphosphate) (RDP) - CAS# 125997-21-9																					
Phosphoric acid, 1, 3-phenylene tetraphenyl ester	57583-54-7	65-80	*L*	*L*	*L*	*L*	nd	*L*	*L*	*M*	*L*	nd	*L*	*M*	*L*	*L*	*H*	*M*	*H*	nd	phenol + resorcinol
Phosphoric acid, bis[3-[(diphenoxy-phosphinyl)oxy]phenyl] phenyl ester	98165-92-5	15-30	*L*	*L*	*L*	*L*	nd	*L*	*L*	*M*	*L*	nd	*L*	*M*	*L*	*L*	*L*	*H*	*L*	nd	phenol + resorcinol
Triphenyl Phosphate	115-86-6	<5	*L*	L	L	L	nd	L	L	M	L	nd	L	M	L	H	*H*	L	M	nd	diphenyl phosphate + phenol
Breakdown Products																					
Phenol	108-95-2		L	M	L	L	L	M	M	H	L	L	H	H	M	M	M	L	L		
Resorcinol	108-46-3		L	L	L	L	M	M	M	nd	M	nd	M	M	nd	M	M	L	L		
Diphenyl phosphate	838-85-7		*Insufficient data for evaluation*																		
Decabromodiphenyl ether (decaBDE) - CAS# 1163-19-5																					
DecaBDE	1163-19-5	97	M	L	L	M	M	M	L	L	L	nd	L	L	nd	L	L	vH	M	penta-to nona-BDE	tri-to nona-BDE
Breakdown Products																					
PentaBDE	32534-81-9		nd	L	M	M	H	M	L	H	L	L	M	M	nd	H	H	vH	vH		
OctaBDE	32536-52-0		nd	L	M	H	M	M	L	H	L	nd	L	L	nd	L	L	vH	M		

ABBREVIATIONS: nd=not determined/unknown; vH=very high concern; H=high concern; M=moderate concern; L=low concern. **Colored bold text** = based on experimental data. ***Black italics text*** = based on analog data or expert judgment.

SOURCES: BPADP and RDP constituents: Syracuse Research Corporation, 2006, *Flame Retardant Alternatives* (prepared for Washington State). All other chemicals: see Appendix 5.

ChAMP Critique

Add Functional Class Information to ACToR

- **Chemical Summary : Triclocarban**
-
- GCID 3431
- CASRN 101-20-2
- Formula C13H9Cl3N2O
- MW 315.5824
- SMILES O=C(Nc(ccc(c1)Cl)c1)Nc(ccc(c2Cl)Cl)c2
- INCHI InChI=1/C13H9Cl3N2O/c14-8-1-3-9(4-2-8)17-13(19)18-10-5-6-11(15)12(16)7-10/h1-7H,(H2,17,18,19)/f/h17-18H
- FUNCTION: bactericide

Evolving Science

- How can we integrate results that capture new information?
  - New test methods
  - New endpoints of interest
    - Epigenetics
    - Broader definition of endocrine disruption

Defer Risk Judgments

- Pending system that permits more use details
- Greater communication between Offices & Agencies
  - Referrals to notify others of high hazard chemical status
- Formulators – commercial and consumer materials, products
- Environmental Releases
  - Emergency Responders
  - Standard Releases
  - Site Remediation

220 Chemicals, Initial Thoughts

- Need more focus on hazard
- Link information to green chemistry by introducing chemical function information
- Use ACToR to compare chemicals of similar function
- Enhanced inter-office and inter-agency communication