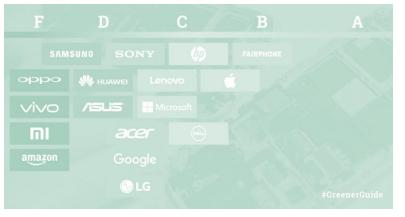
Safe Harbor Levels

Chermicals, The Electronics industry, and Control: No Significant Risk Level (NSRL) - Oral: 15 µg/day Reproductive Toxicity Why A New Discipline is Needed -Melealthab& Environment Safety Engineering (HESE) Last NSRL/MADL Revision: 201





WARNING: Reproductive Harm - www.P65Warnings.ca.gov

Michael Kirschner Design Chain Associates, LLC Compliance & Risks Webinar 12 February 2019



Agenda

- Introduction
- The Problem
- Case Study:
 - Flame Retardants
- The Implications & The Industry's Challenge
- Recommendations



About DCA

Manufacturing Consulting firm

Focus on Discrete/Fabricated "Article" Manufacturers

Based in San Francisco, CA

- Main Focus: Strategies/Tactics for Compliance with Product-focused Environmental Regulation & Customer Requirements
 - Substance Restriction/Disclosure Compliance, Recycling, Green Claims, Energy Use, Conflict Minerals, Carbon/GHG, NGOs/Retailers
 - Worldwide scope
 - A&D, Industrial and Commercial, Consumer, Medical, Apparel, Agriculture, Construction, etc.

See www.DesignChainAssociates.com



Mike's Background

20 years in manufacturing companies, in product development and quality/reliability roles:



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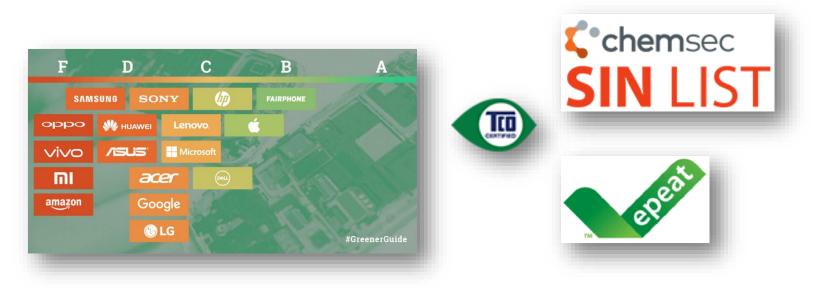
DESIGNCHAIN

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Problem

Historically – and at worst – <u>chemical toxicity in</u> <u>manufactured articles</u> has been treated as Somebody Else's Problem

At best, we are treating chemical environmental and health toxicity as a performance issue



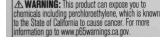


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Competition Doesn't Sway Governments

Governments demand that industry address it

- Industry grudgingly reacts
- Industry does not view it as a sellable parameter like
 - Speed
 - Gigabytes/Second
 - Teraflops
 - Sexiness
 - ≻ Etc.



ANNEX XVII

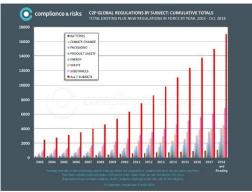
RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, MIXTURES AND ARTICLES



For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction	
1. Polychlorinated terphenyls (PCTs)	Shall not be placed on the market, or used:	
	— as substances,	
	 in mixtures, including waste oils, or in equipment, in concentrations greater than 50 mg/kg (0.005 % by weight). 	







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The Result

Industry's reactive approach is ... suboptimal



Suboptimal?

When a substance is restricted, manufacturers replace it based primarily on these factors



Toxicity – the rationale for the restriction – is generally not a primary, or often even a secondary, consideration

Result: The technical requirement is addressed but the problem is not, or it is poorly addressed

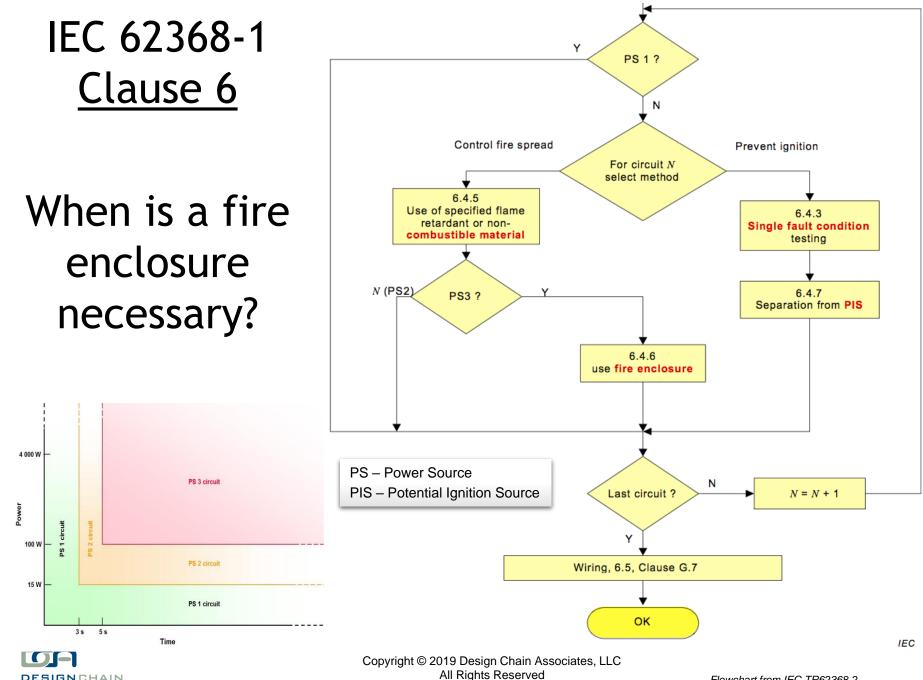


Case Study: Flame Retardants are used in Plastics

To Meet Flammability Safety goals defined in product safety standards, for example IEC (or UL) 62368-1

- (IEC/UL 62368-1 covers IT/Video/Audio; other standards cover other categories of electronics)
- IEC: International Electrotechnical Commission international standards body
- UL: Underwriters Lab US-focused standards

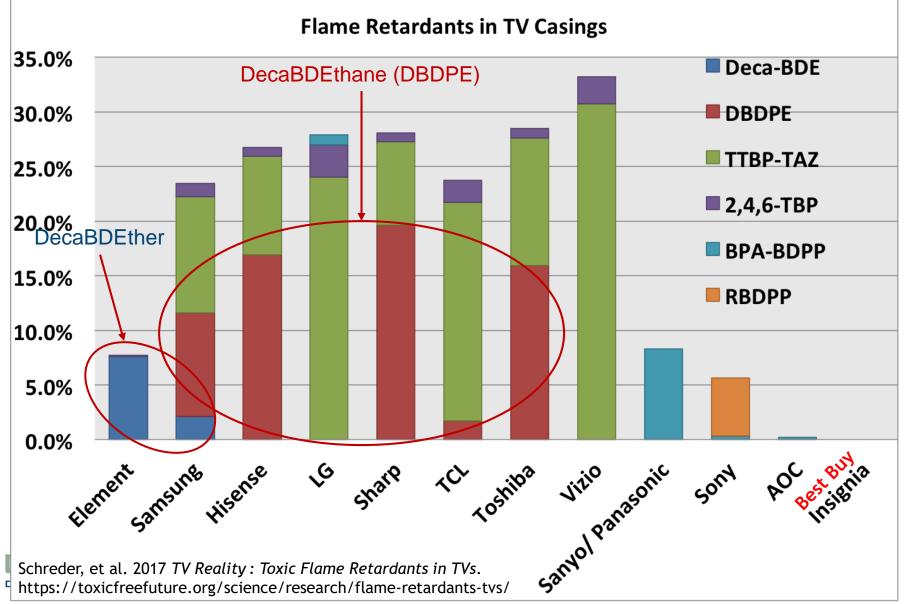




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Flowchart from IEC TR62368-2

Flame Retardants Used in TV Enclosures Sold in the US



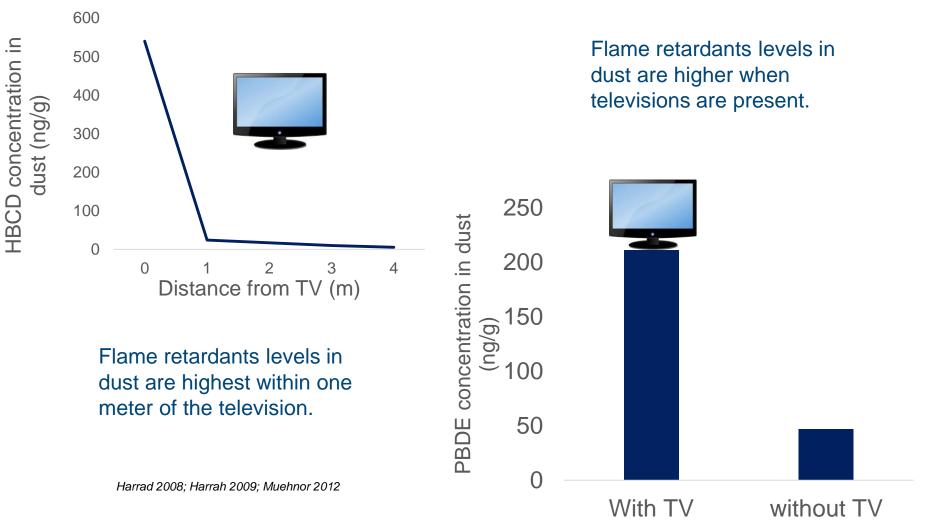
Flame Retardants Used in US TV Enclosures

Proposed for Restriction in Canada!	Restricted or Declarable in EU, California, Illinois, Minnesota, New Jersey, New York, Washington, etc.!!		
Chemical Name	Acronyn	CAS #	Туре
Decabromodipheryl ether	Deca-BDE	1163-19-5	brominated
Decabromodiphenyl ethane	DBDPE	84852-53-9	brominated
1,3,5-Triazine, 2,4,6-tris(2,4,6-tribromophenoxy)	TTBP-TAZ	25713-60-4	brominated
Octabromotrimethylphenylindane	OBIND	1084889-51-9	brominated
2,4,6-tribromophenol	2,4,6-TBP	118-79-6	brominated
Resorcinol diphosphate	RBDPP	125997-21-9	phosphate
Bisphenol A bis-(diphenylphosphate)	BPA-BDPP	5945-33-5	phosphate

Schreder, et al. 2017 *TV Reality : Toxic Flame Retardants in TVs.* https://toxicfreefuture.org/science/research/flame-retardants-tvs/



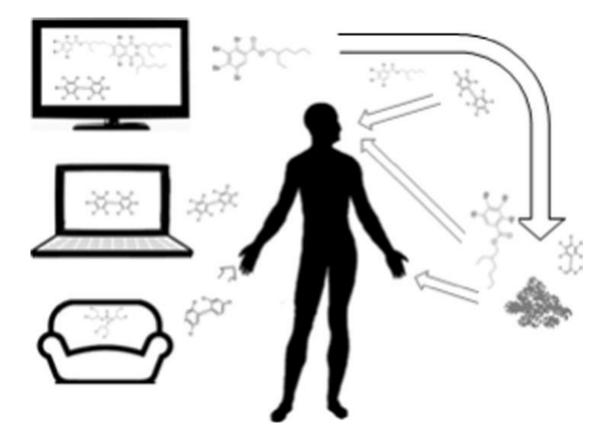
OrganoHalogen Flame Retardants Migrate from Electronics into Dust





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OHFRs from Electronics are Absorbed by People



Source: Diamond, "Product screening for sources of halogenated flame retardants in Canadian house and office dust," 2016.



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PETITION HP 15-1

to the U.S. Consumer Product Safety Commission

...Requesting Rulemaking on Products Containing Organohalogen FRs

Declare as "banned hazardous substances" any:

- Children's products
- Residential furniture
- Mattresses & mattress pads
- Plastic electronics enclosures

containing additive, non-polymeric organohalogen flame retardants

• 13 supporting statements from scientists and health professionals



PETITION HP 15-1

to the U.S. Consumer Product Safety Commission

Declare as "banned hazardous er 20 September 201 • Children's products • Residential furn. • GRANTED

- Mattresses & mattress pads
- Plastic electronics enclosures

containing additive, non-polymeric organohalogen flame retardants

13 supporting statements from scientists and health professionals



gen FRs

Sept. 28, 2017

"[T]he Commission recommends that manufacturers of children's products, upholstered furniture sold for use in residences, mattresses (and mattress pads), and <u>plastic casings surrounding electronics</u> refrain from intentionally adding non-polymeric, organohalogen flame retardants ("OFRs") to their products."

> "Numerous peer-reviewed, published studies show that the vast majority of consumers have measurable quantities of OFRs in their blood."



"...the Commission has serious concerns regarding the potential toxicity of OFRs, and the risks of exposure, particularly to vulnerable populations..."

-Federal Register Notice on Additive, Non-Polymeric Organohalogen FRs

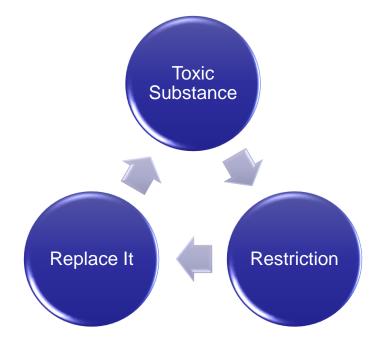
https://www.federalregister.gov/d/2017-20733



The Effect of IEC/UL 62368-1 Clause 6

- Clause 6 of IEC/UL 62368-1 helps safety engineers define design requirements to meet fire (and other) safety goals for IT/Video/Audio equipment
 - > As do other standards for other types of Electrical/Electronic Products
- It does not define the "right" approach
 - Or what "right" means!
- It does not specify materials to use or the use of FRs
 - Or whether/how to assess those materials for environmental/human health/biological safety
- If implemented correctly, the product will pass the <u>defined</u> test
 - > But it may not be "safe" in terms of the environment or human health





And That Leads to Regulation

Because we end up (unintentionally) designing toxic substances into products



Why Does This Happen?

- Chemicals and chemical toxicity are not a typical design constraint: <u>Product Safety Standards do not address it!</u>
- Manufacturers define a "Safe Design Space" process
 - Places market, cost, size and other constraints on product design, development & marketing based, in part, on safety standards
 - Adding Heath & Environmental Safety or any other Constraints shrinks the "Gray Area" and "Acceptable" spaces





Product Safety vs. Health/Env Safety

These are not mutually exclusive

- FR example: meeting flammability safety requirements can have negative human health/environmental safety (HES) impacts
- We are not solving the safety problem: we are displacing it from fire safety to HES
 - Product Safety review and assessment *must* incorporate HES impact assessments; they do not at most manufacturers
 - > The HES assessment must go beyond regulatory requirements
 - Regulations lag far behind a chemical's release to the market



Parallels to Other Customer Expectations

- No overt demand for HES: Consciously or not, customers simply expect
 - "Safe" Products
 - Electromagnetic Interference under control
 - Quality
 - Reliability
 - Cybersecurity => Data Safety
- Problems in some of these areas result in regulation
- Industry response is, in some, to create standards
 - Levels playing field for areas manufacturers prefer not to compete in
 - Note that we don't have product category-specific standards for quality, reliability or cybersecurity goals



The Industry's Challenge

- To implement a new constraint like this requires chemical and toxicological expertise
 - The electronics industry, like most industries so far downstream of the chemical industry, lacks expertise
- Manufacturers today are simply reacting to environmental/health safety requirements placed on it
 - By regulators
 - By retailers
- Few have the expertise to be proactive



Nothing will change unless we "get a seat at the table"

- Dramatically expand our knowledge and its availability in this space
- Work with, instead of against, NGOs and governments



Health & Environmental Safety Engineering

HESE: A formal product safety discipline, like

- > Thermal, mechanical, electrical, optical, acoustic, etc...
- Focused on defining and meeting product environmental, biological and human health safety requirements
- Corporate Level:
 - Part of Product Safety Engineering/Engineering Services
 - Built upon existing product compliance/stewardship function
- Industry Level:
 - Membership organization to solidify HESE and create community
 - Standards Development Organization (SDO) to define and develop appropriate standards



Key Challenges

- 1. Expertise sparse, localized
- 2. ECHA/EU MS Resources how to compete or stand up to them?
 - Depending on the chemical industry for support is risky, if not foolhardy
- 3. Long-Term & Readily out-prioritized for funding
- 4. No Data/No Standard difficult to make consistent decisions
 - Treading water by being reactive is, therefore, the norm



Summary/Recommendations

- Health & Environmental Safety <u>must</u> be viewed as a design constraint
 - Product Safety Engineering must work closely with HESE personnel
 - > HESE must have a voice in product development and supplier/material selection
- Product Safety Standards define product safety expectations
 - But, aside from acute issues, they do not specify HES expectations
 - Formalizing another safety discipline is the first step toward closing this gap
- Recommendations to manufacturers:
 - Hire the necessary expertise
 - Work together to formalized the Health/Environmental Safety discipline
 - Fund and populate it to properly define scope, requirements and desired output



Thank You For Your Attention



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Mike@DesignChainAssociates.com 415.342.3217



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Appendix <extra slides>



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What is an OrganoHalogen?

Organic compound:

 Classically, a molecule that contains carbon

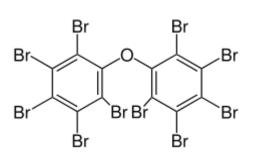
Halogen:

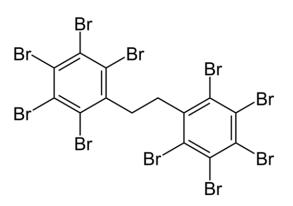
- Periodic Table Group containing
 - Fluorine
 - Chlorine
 - Bromine
 - Iodine
 - Astatine

Organo-Halogen Flame Retardants (OHFRs):

- Chlorine, Bromine, or Fluorine-based
- Inhibit or delay spread of flame







Decabromodiphenyl ether

Decabromodiphenyl ethane

OHFRs are Not Federally Banned Yet!

Only Guidance For Now from CPSC Regulation is Yet To Come

