From Reaction to Prevention: Science to Rapidly Prioritize Chemicals and Support the Transition Towards Safer Chemicals, Processes, and Products

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Overview

- Elements of Comprehensive Chemicals Policy
- Limitations of Risk-Based Science-Policy Framework
- The need for a new science-policy approach
- Elements of the new paradigm
- Conclusions
Elements of comprehensive chemicals policies

- Comprehensive and inclusive of all chemicals
- Create and provide access to health and environmental information along supply chains and to the public
- Classify chemicals into categories for specialized response
- Hazard-based rather than exposure-based
- Transition chemical use from high-hazard to lower-hazard substances
- Promote research, innovation, and green chemistry
Three areas of transformation needed to achieve comprehensive chemicals policy

- Policy transformation
- Market transformation
- Science transformation
Evolving Chemicals Knowledge

From Large Industrial Emissions…
- Point sources, facility specific, media specific (air, water, waste)
- Few identified chemicals of concern
- Policy tools: End-of-pipe controls, permitting, monitoring, risk-based standards

To a Broad Range of Product-Based Emissions.
- Smaller, disperse, non-point, difficult to control, different toxicological mechanisms
- Many identified chemicals of concern
- Policy tools: Redesign, green chemistry, substitution, safer alternatives
Current Process for Risk-Based Chemical Decision-Making

- Define the problem and determine data needs
- Gather data and determine if there is a need for further data
- Conduct quantitative risk assessment
  - Hazard assessment
  - Exposure assessment
  - Dose-response assessment
  - Risk characterization
- Determine if risk is “acceptable” or if exposure is “safe”
- Make decision about further study, exposure controls, use restrictions, etc.
Limitations of Risk-Based Science-Policy Framework

- Problem-basis
  - Reactive, does not consider preventability
  - Chemical by chemical
- Costly, slow – few assessments actually done
- Rarely consider qualitative or non-quantitative information – “push for a number at the expense of thinking.”
- Rarely considers cumulative or multiple exposures or susceptible sub-populations
- Ignores intrinsic lifecycle hazards – snap shot in time
- Assumption of a data-rich environment and increasingly complex quantitative methodologies
- Assumes a comprehensive scientific understanding is necessary to allow informed decisions to occur
Results of this approach

- Lack of evidence and information being (mis-) interpreted as evidence of safety.
- Uncertainty in risk assessments a reason for more study and delay. De facto presumption of harmlessness and more uncertainty leads to more study.
- Failure to consider alternatives and design.
- While continued research will help fill knowledge gaps, government officials have a responsibility to act to reduce hazards when sufficient evidence of possible harm exists.
- Example: Methylene Chloride Occupational Health Standard; Dioxin and Trichloroethylene risk assessments.
Conclusions on the current science-policy approach

- There are simply far too many chemicals with poorly understood health effects already on the market for any reasonable expectation that science can adequately measure the risk of each one.

- Stringent application of the current regulatory approach – in which the government or others calculate risks one at a time and develop regulations for each chemical – cannot be effective against the complexity of the synthetic chemicals in our environment.
Need for a new science policy paradigm based on solutions

- From “Science-Based” to “Science Informed”
- Focus on what opportunities exist for steering the design, production, and use of technologies away from damage.
- Most rapidly achieved through incremental introduction of alternatives and solutions without waiting for comprehensive knowledge.
- Requires tools for more rapid characterization of problem sphere. Focus on intervention points rather than full knowledge
- Move from characterizing problems to characterizing needs and solutions – bring science and action together.
- Given the possibility that x causes y, is there a way to move toward more sustainable practice by replacing x while preserving its benefits? Lower threshold to act.
“All scientific work is incomplete – whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action that it appears to demand at a given time.”
Elements of a new approach to the use of science in chemicals decision-making

- Rapid Prioritization and Decision-Making on Chemicals
- Alternatives Assessment
- Design of Safer Chemistries – Green Chemistry
Definitions of hazard, use, and exposure

- **Hazard:** *Intrinsic properties based on molecular structure*. For example persistence, carcinogenicity, neurotoxicity. Regardless of how used. Can focus on avoiding hazards of concern.

- **Use:** *Discrete application of a substance*. Includes how it is used (functional use – solvent) and the way in which it is used (consumer product, workplace)

- **Exposure:** *Relationship between substance and target*. Who is exposed and how they are exposed (vulnerable populations, etc.). Often difficulty to obtain

- Each has particular measures and proxies
Benefits of Rapid Prioritization and Decision-Making on the Basis of Hazard, Use, and Exposure Information

- Provides greater accountability
  - Provides clarity about the nature of the evidence on hazards, exposures, and uses as well as trade-offs involved
  - Transparency in choices in the analysis
- Opens up greater opportunities for prevention and intervention.
  - Provides three points of intervention – reduce hazard, change use and control exposure
  - Greater understanding of the nature of potential impacts, trade-offs and opportunities for prevention in decision-making
  - Ability to categorize chemicals for actions
  - Pinpoint nature and types of uncertainties
- Allows for rapid screening and prioritization in the absence of perfect data
Consistency of Rapid Prioritization Approach with Prevention Frameworks

- **Industrial Hygiene Hierarchy**
  - Elimination of the Hazard
  - Substitution
  - Engineering Controls
  - Administrative Controls
  - Personal Protective Equipment

- **Pollution Prevention Act Hierarchy**
  - Prevention/Source Reduction
  - Recycling
  - Treatment
  - Disposal
The Green Screen for Safer Chemicals

- Guidance for selecting greener chemicals
- Case Study: FRs used in television casings
  - decaBDE,
  - RDP
  - BPADP

**Benchmark 1**

- PBT: high P + high B + high T¹ (high Human Toxicity² or high Ecotoxicity)
- vPvB: very high P + very high B
- vPT (vP + high T) or vBT (vB + high T)
- high Human Toxicity for any priority effect²

**Avoid—Chemical of High Concern**

**Benchmark 2**

- moderate P + moderate B + moderate T
  (moderate Human Toxicity or moderate Ecotoxicity)
- high P + high B
- (high P + moderate T) or (high B + moderate T)
- moderate Human Toxicity for any priority effect or high Human Toxicity
- high Flammability or high Explosiveness

**Use but Still Opportunity for Improvement**

**Benchmark 3**

- moderate P or moderate B
- moderate Ecotoxicity
- moderate Human Toxicity
- moderate Flammability or moderate Explosivenessness

**Benchmark 4**

Ready biodegradability (low P) + low B + low Human Toxicity + low Ecotoxicity
(+ additional ecotoxicity endpoints when available)

Prefer—Safer Chemical

If this chemical and its breakdown products pass all of these criteria, then move on to Benchmark 4

If this chemical and its breakdown products pass all of these criteria, then move on to Benchmark 3

If this chemical and its breakdown products pass all of these criteria, then move on to Benchmark 2
Industry Efforts on Rapid Screening

- Tools to assess and prioritize chemicals and products
- Restricted Substances Lists
- Reformulation of products and product design strategies to eliminate chemicals of concern
- Ingredient disclosure
- Chemical use policies
GreenWERCS Chemical Screening Tool

- Analyzes the composition of individual products from ingredient data entered by manufacturers
- Identify and reduce chemically hazardous products
- Helps make informed decisions based on:
  - Chemicals harmful to human health
  - Chemicals harmful to the environment
  - Sustainability goals
Domestic Substances List
Categorization and Screening Program

One of the initiatives in the Canadian Environmental Protection Act, 1999 (CEPA 1999) requires the Minister of the Environment and the Minister of Health to "categorize" (Section 73, CEPA 1999) and then if necessary, conduct screening assessments (Section 74, CEPA 1999) of substances listed on the Domestic Substances List (DSL) to determine whether they are "toxic" or capable of becoming "toxic" as defined in the Act. Under the Act, a substance is "toxic" if it is entering or may enter the environment in a quantity or concentration or under conditions that:

(a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;
(b) constitute or may constitute a danger to the environment on which life depends; or
(c) constitute or may constitute a danger in Canada to human life or health.

The DSL includes substances that were, between January 1, 1984, and December 31, 1986, in Canadian commerce, used for manufacturing purposes, or manufactured in or imported into Canada in a quantity of 100 kg or more in any calendar year. The purpose of the List was to define what was 'New to Canada' and it has been amended from time to time following assessment under the New
Figure 1.3: Risk factors
Screening Method: Quick Scan

*Dutch Strategy on Management of Substances, 2001
Screening Method: Quick Scan

### Substances in concern category on basis of hazard and use

<table>
<thead>
<tr>
<th>CONCERN ON BASIS OF HAZARD</th>
<th>EXPOSURE ON BASIS OF USE</th>
<th>Use of substances as indication of exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very high concern</td>
<td>High concern</td>
<td>High concern</td>
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<tr>
<td>High concern</td>
<td>Concern</td>
<td>High concern</td>
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<tr>
<td>Low concern</td>
<td>Concern</td>
<td>Concern</td>
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<tr>
<td>No data, very high concern</td>
<td>Very high concern</td>
<td>Very high concern</td>
</tr>
</tbody>
</table>

- Site limited intermediate substances
- Substances in industrial applications
- Open professional use of substances
- Substances in consumer applications
- Low exposure
- High exposure
- Very high exposure

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### Table 4-1: Screening Level Toxicology and Exposure Summary

<table>
<thead>
<tr>
<th>Company</th>
<th>Chemical*</th>
<th>% in Formulation</th>
<th>Human Health Effects</th>
<th>Ecotoxicity</th>
<th>Environmental</th>
<th>Potential Routes of Exposure</th>
<th>General Population</th>
<th>Re却ic or Additive?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albemarle</td>
<td>ANTIBLAZE 180 and ANTIBLAZE 195</td>
<td>95%</td>
<td>M L M M LM M M M M</td>
<td>L</td>
<td>N Y Y Y N Y Y Y Y</td>
<td>Additive</td>
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<td>Albemarle</td>
<td>ANTIBLAZE 192 and ANTIBLAZE 205</td>
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<tr>
<td>Proprietary A</td>
<td>Chloroalkyl phosphate (1)</td>
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<tr>
<td>Proprietary B</td>
<td>Aryl phosphate</td>
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<td>Triphenyl Phosphate CAS # 115-86-6</td>
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<td>Albemarle</td>
<td>ANTIBLAZE V500</td>
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<td>Proprietary C</td>
<td>Chloroalkyl phosphate (2)</td>
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<td>Proprietary B</td>
<td>Aryl phosphate</td>
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<tr>
<td>Albemarle</td>
<td>SAYTEX RX-8500</td>
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<td>Proprietary D</td>
<td>Reactive brominated flame retardant</td>
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</table>

*L = Low hazard concern, N = No, M = Moderate hazard concern, Y = Yes, H = High hazard concern, P = Yes for pure chemical

*Ongoing studies may result in a change in this endpoint

*Persistent degradation products expected
Alternative Ways of Thinking about Chemicals Problems and Science
What to Consider in Alternatives Assessment

- The **purpose** of the activity – need, service/ functionality
- Develop **criteria** (presumptions) for activities that should be avoided or **principles** that guide tech. development – (eg. Green chemistry)
- Understand flow of the material or activity, characterize **process/lifecycle/systems**
- Brainstorm a **wide range** of potential (existing/ on horizon) alternatives to meet a need or function – “move from just a little less bad”
- Implement/transition to the best alternative – understanding the research and tech support and safety measures that need to be implemented
- **Monitor** and **change course** as needed – identify early warnings and continuous improvement
- **Technology assessment** - developing comprehensive understandings of new technologies and activities
Alternatives Assessment Example: 
MA Toxics Use Reduction Act

- List of chemicals for which companies must report materials throughput annually and undertake alternatives planning every two years.

- Toxics Use Reduction and Trichloroethylene in Massachusetts
  - Focus on understanding why and how use materials
  - Evaluation of alternatives
  - Technical and research support for application
  - Continuous improvement
Use Data: TCE in Massachusetts

- 1990: 2.5 millions of pounds
- 1996: 1.5 millions of pounds
- 2001: 1 million of pounds
- 2002: 0.5 million of pounds

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Moving toward safer design – Green Chemistry and Design for Environment

- The utilization of a set of 12 principles that reduces or eliminates the use or generation of hazardous substances in the design, manufacture and application of chemical products.
- Focuses on “hazard reduction” in chemical, process and product design as a primary goal.
- Seeks to unite government, academic and industrial communities by focusing on environmental impacts at the earliest stage of innovation and invention.
- Applied through Design for Environment, an approach that encourages consideration of environmental and health considerations in the design and redesign of products – informed substitution.
Michigan Green Chemistry Executive Directive

EXECUTIVE DIRECTIVE No. 2006-6

PROMOTION OF GREEN CHEMISTRY FOR SUSTAINABLE ECONOMIC DEVELOPMENT AND PROTECTION OF PUBLIC HEALTH

Advancing Green Chemistry:
An Action Plan for Michigan Green Chemistry Research, Development, and Education

September 2008

greenUp
Michigan Green Chemistry Conference

Department of Environmental Quality
Lowell Center for Sustainable Production
“In a few decades it won’t be special anymore... Everyone will be doing green chemistry.”
Professor Robert H. Crabtree
Yale University
Chemistry Department
Needs to support transition towards a new approach to the use of science in chemicals decision-making

- Information
  - Hazard, Uses (ingredients), Potential Exposures
  - Materials flows in products and processes

- Tools
  - To integrate toxicity considerations at the design phase
  - To rapidly assess hazards and exposure potential
  - To compare alternatives on basis of toxicity, performance, cost – how define “safer”?

- New decision-making processes
  - Consideration of hazards, use, exposure and alternatives in determining appropriate actions
  - Flexibility to adapt decisions to available knowledge
  - Avoid unnecessary and protracted debates over uncertainties in risk assessments
Conclusions

- Current approaches to the use of science in chemicals decision-making are slow, costly, reactive and do not generally support transition to safer chemicals and products.

- A more efficient, proactive and solutions oriented approach to chemicals science and decision-making consists of:
  - Rapid prioritization and decision-making on the basis of hazard, use, and exposure information
  - Alternatives assessment
  - Design of safer chemicals

- We still need much science to characterize risks but need to put equal resources into developing solutions.
Conclusions

- **Benefits of this approach**
  - acknowledge evolving understanding of chemicals (hazards, uses, design);
  - assess and act on more chemicals more rapidly;
  - provide greater certainty to manufacturers;
  - support innovation and transition to safer materials