Class 9: As a starting position in social decision-making structures, should chemicals be assumed to be hazardous or not hazardous?

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Decision-Making Structures in the Law

The **burden of proof** is assigned to one party to provide sufficient information for the decision-maker to reach a decision in their favor. That party and will lose if:

1. **there is no information on the issue** or
2. **information does not resolve the issue.**

A **default assumption** is created by allocation of the burden of proof.

### 1. Chemical water pollutant in drinking water under common law tort of nuisance.

- **Burden of proof:** Plaintiffs must prove harm, and that defendant was unreasonable.
- **Default assumption:** Not harmful, defendant not unreasonable

### 2. Industrial chemicals under Toxic Substances Control Act.

- **Burden of Proof:** Government must show chemicals present unreasonable risk
- **Default assumption:** Industrial chemicals not unreasonably harmful.


- **Burden of Proof:** Manufacturers must prove safe and effective.
- **Default assumption:** Pharmaceuticals not safe and effective.

### 4. Industrial chemicals under the EU’s REACH (authorization for CMR’s, PBT’s).

- **Burden of Proof:** Manufacturer must show socioeconomic benefit of CMR, PBT.
- **Default assumption:** CMR’s, PBT’s do not have positive socioeconomic benefit.
Assume Chemicals Are Hazardous?

Factors Courts/Legislators Consider in Allocating the Burden of Proof (Specifying Default Assumption)

1. Allocate to the party that has unique access to the relevant information or is in the best position to obtain or develop or obtain it.

2. Policy Objectives: Default protects an interest -- this should be the interest society prefers to protect. Default defines which type of error is preferred.

3. Estimate of the probabilities: Default should be the outcome most likely to be correct.
“Today, all of the materials we work with and interact with, almost 90 percent, somewhere along the way uses some hazardous solvent or some reagent or some such in part of the process.”

John Warner, 2007
in Compliance Side Total Chemical Management Today
Not enough information is available on how many of the approximately 30,000 substances currently estimated to be covered by the REACH proposals have dangerous properties. [...] However, of the new substances assessed under existing EU legislation around 70% have been shown to have one or more dangerous properties. An unknown but potentially significant proportion of all chemical substances will enter the environment and reach sufficiently high concentrations to induce adverse effects.”

In 2006, Environment Canada and Health Canada completed the “categorization” of approx. 22,400 chemicals on the Domestic Substances List. 4,350 chemicals — about 20% — were categorized for further screening-level risk assessment.
“Today, all of the materials we work with and interact with, almost 90 percent, somewhere along the way uses some hazardous solvent or some reagent or some such in part of the process.” — John Warner

“[...] of the new substances assessed under existing EU legislation around 70% have been shown to have one or more dangerous properties. An unknown but potentially significant proportion of all chemical substances will enter the environment and reach sufficiently high concentrations to induce adverse effects.” — European Commission

In 2006, Environment Canada and Health Canada completed the categorization of approx. 22,400 chemicals on the Domestic Substances List. 4,350 chemicals — about 20% — were categorized for further screening-level risk assessment.
What proportion of industrial chemicals do you believe are likely to present some degree of hazard to human health or the environment?
Canada’s categorization of substances: What were they looking for?

73. (1) The Ministers shall, within seven years from the giving of Royal Assent to this Act, categorize the substances that are on the Domestic Substances List by virtue of section 66, for the purpose of identifying the substances on the List that, in their opinion and on the basis of available information,

1. (a) may present, to individuals in Canada, the greatest potential for exposure; or
2. (b) are persistent or bioaccumulative in accordance with the regulations, and inherently toxic to human beings or to non-human organisms, as determined by laboratory or other studies.
Canada’s categorization of substances: What were they looking for?

Source: Environment Canada
Canada’s categorization methods

**Persistent**
- $t_{1/2}$ (air) $\geq$ 2 days
- $t_{1/2}$ (water) $\geq$ 6 months
- $t_{1/2}$ (sediment) $\geq$ 1 year
- $t_{1/2}$ (soil) $\geq$ 6 months

**Bioaccumulative**
- BAF $\geq$ 5000
- or BCF $\geq$ 5000
- or log $K_{OW} \geq$ 5

**Inherently toxic to environment**
- Acute aquatic toxicity: LC50 (EC50) $\leq$ 1 mg/L
- Chronic aquatic toxicity: NOEC $\leq$ 0.1 mg/L

**Human health categorization methodology:**

**Large set identified by:**
- Persistent OR Bioaccumulative AND iT$_E$
- “Simple Exposure Tool”
  - Production volume, distribution
  - Use categories
- “Simple Hazard Tool”
  - Lists of known hazards from other jurisdictions

**Refined & prioritized set using:**
- “Complex Hazard Tool”
- Search for available data on a hierarchy of hazard traits: carcinogenicity, mutagenicity, developmental toxicity, reproductive toxicity, long-term, short-term, acute.
- Numeric criteria for evaluation
What does “on the basis of available information” mean?

<table>
<thead>
<tr>
<th>11,317 organic substances</th>
<th># chemicals with experimental data available</th>
<th>% experimental data of acceptable quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>persistence</td>
<td>410</td>
<td>~25%</td>
</tr>
<tr>
<td>bioaccumulation</td>
<td>850</td>
<td>~33%</td>
</tr>
<tr>
<td>inherent toxicity to nonhuman organisms</td>
<td>1,051</td>
<td>~75%</td>
</tr>
</tbody>
</table>

Data gaps were addressed by
• Using predictive models and quantitative structure-activity relationships;
• Using expert judgment;
• Not categorizing the substance due to lack of data (several hundred).

The goal was to affirmatively identify chemicals that fit the criteria.
Health DSL Categorization/Prioritization

September 2006
Health Priority Setting

Oct. 2004
Health Draft Maximal List

High or Intermediate Exposure (~100)
- Low Exposure (~160)
- Petroleum Streams
  - High/Intermediate Exposure (~160)
  - Low Exposure (~100)

High Health Priorities for Action - High Hazard Substances

Moderate Priorities - GPE or IPE and persistent and/or bioaccumulative (~630)
(Petroleum streams ~50)

Moderate Health Priorities for Action - Hazard Unknown

Substances (~760) not requiring further work for human health at this time

Source: Health Canada
What does the 20% figure mean? Are the other 80% of chemicals safe?

Is it possible to prove that a chemical is safe?

Has your estimate changed for what proportion of chemicals are likely to present a hazard?
Are chemicals likely enough to present some threat to human health or the environment that chemical producers should be required to go to the expense of testing them?

Consider:

• Economic impacts of requiring companies to produce data. Will the data be worth the costs?
• Impacts on the rate and quality of innovation in the development of new materials and technologies.
• Is there a reasonable minimum amount of data that can be used to set a useful standard of safety?
Status of Environment on Global or Ecosystem Scale

- Limits to Growth

- Planetary Carrying Capacity

- Declines in ecosystem functioning services, biodiversity etc.

Millennium Ecosystem Assessment, United Nations (2005)

Humanity in the Anthropocene


Steffen, W., et al. 2004
Planetary Boundaries

Exploring the Safe Operating Space for Humanity

Prof. Johan Rockström
Stockholm Resilience Centre
The Resilience of the Earth System
From:
"Limits to growth"
"Carrying capacity"
"Guardrails"
"Tipping Elements"

To:
"Planetary Boundaries"
Planetary Boundaries

- Climate Change
- Ozone depletion
- Atmospheric Aerosol Loading
- Ocean acidification
- Global Freshwater Use
- Chemical Pollution
- Global N & P Cycles
- Land System Change
- Rate of Biodiversity Loss
- Biogeochemical loading: Global N & P Cycles
Conclusions

• In the Anthropocene Humanity is, for the first time, influencing hard-wired processes at the Earth System scale.

• We define the **Holocene as the desired stable state** providing necessary environmental pre-conditions for human development.

• **We need a new approach to global sustainability and development.** Scientific insights from research on resilience and complex systems, and Earth System Science, on the risks of human induced tipping points in a multitude of Earth system processes and sub-systems.

• We propose that a **Planetary Boundary framework** may provide one step towards this necessary redefinition.
Chemical Pollution
Steer away from irreversible impacts on living organisms

- Global, ubiquitous impact on the physiological development and demography of humans and other organisms with ultimate impacts on ecosystem functioning and structure
- By acting as a slow variable that affects other planetary boundaries (e.g., rate of biodiversity loss)
- 2 complementary approaches: amounts of persistent pollutants with global distribution (e.g., mercury); Effects of chemical pollution on living organisms
- Difficult to find an appropriate aggregate control variable. Close interactions with Aerosol loading; may require sub-boundaries based on sub-impacts/categories of chemicals
Assume Chemicals Are Hazardous?

**Chemical Pollution as Planetary Boundary**

1. Theoretically, is there a boundary (threshold) for ecological toxic load?

2. How should that threshold be defined?

3. If there is a threshold, how will we know when we are close to it?

4. Should chemists designing new chemicals consider this in their work?

5. What should society do about this in designing chemicals policy?