MOVING FROM RISK-DRIVEN CHEMICALS POLICIES TO TECHNOLOGY-BASED SOLUTIONS

The opportunity of paradigm shifting when inter-individual variability becomes a major concern in regulatory policy

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Percent first exhibiting a harmful effect

Atopy

B

C

CI

Classical Toxicity

Dose

A
1. Many different kinds of chemicals cause response
2. Many different responses involving any and every organ system
3. Specific mechanisms may vary greatly
4. Probably no single biomarker for responses; identification of biomarkers may take years
5. Prevention (avoidance) may precede knowledge of specific
A Regulatory Decision-Making Framework

- Questions of *Whether, Where, When, How,* and *to What Extent* to intervene:
  - notify those (possibly) affected
  - regulate exposure; control or limit production
  - eliminate production or use
  - treat those impacted
  - compensate for harm

- What are the criteria for deciding?
- What strength of evidence triggers a requirement for what action? Who has the burden of persuasion?
- What is the importance of classical uncertainty, indeterminacy, and ignorance?
- How does inter-individual variability affect our approach?
<table>
<thead>
<tr>
<th>EFFECTS Group</th>
<th>Economic Effects</th>
<th>Health/Safety Effects</th>
<th>Environmental Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Producers</td>
<td>( C_S )</td>
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</tr>
<tr>
<td>Workers</td>
<td>( C_S )</td>
<td>( B_{H/S} )</td>
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<tr>
<td>Consumers</td>
<td>( C_S )</td>
<td>( B_{H/S} )</td>
<td></td>
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<tr>
<td>Others</td>
<td>( C_S )</td>
<td>( B_{H/S} )</td>
<td>( B_{ENVIRONMENT} )</td>
</tr>
</tbody>
</table>
Considerations Relevant to Decisions about Health, Safety, and the Environment

- the seriousness and irreversibility of the harm addressed
- difficulties in assessing risk comprehensively, e.g., global climate disruption, genetic modification, large inter-individual variability
- Legal mandates to protect the susceptible or sensitive
- the societal distribution of possible costs and benefits of policies and technologies
- the technological options for preventing, arresting, reversing, or mitigating possible harm -- and the opportunity costs of selecting a given policy option.
- society's inclinations regarding erring on the side of caution and erring on the side of laxity
  » with regard to risk
  » with regard to stimulating new technology adoption or development
TYPES OF INFORMATION

● Scientific Information
  » Product ingredients and composition of pollution in air, water, waste and the workplace
  » Toxicity and safety hazard of the substances of concern
  » Exposure to harmful substances and processes
  » => Risk Characterization
  » Inter-individual variability

● Technological Information
  » **Existing technology options** for controlling or preventing pollution, waste, and chemical accidents, i.e., available substitute inputs, final products, and processes that could be adopted => costs (static assumptions)
  » **Technology that could be developed** => costs (dynamic assumptions)

● Legal Information
  » Notification of the rights and obligations of producers, employers, consumers, workers, and the general public
MAKING DECISIONS ABOUT
ENVIRONMENTAL RISK:
COSTS OF CONTROL AND RISK REDUCTION

Cost

Demand for
Risk Reduction

Best Available
Technology

Diminishing
Returns

C = B

Existing
Technology

0
R2
R1
Risk
AN INNOVATIVE RESPONSE TO REGULATION

MAXIMUM ALLOWABLE RISK UNDER REGULATION

NEW TECHNOLOGY
EXISTING TECHNOLOGY

COST

RISK
An Innovative Response to Regulation
An Innovative Response to Regulation

Cost

Maximum Allowable Risk Under Regulation

Demand for Risk Reduction

Pre-regulatory Level of Risk

Existing Technology

New Technology
Using Analysis to Improve the Precautionary Principle

● Minimizing Uncertainty
  » through refinement of (comparative) Risk Analysis
  » through undertaking (comparative) Technology Options Analysis – safer inputs, production methods, and final products

● Attitudes towards Error Avoidance (whether and to what extent to intervene)
  » Risk avoidance (Type I vs. Type II errors regarding requirements for the reduction of risk) [Is it possible to decrease Type II errors without increasing Type I errors? That is, the delay in getting more risk information could create harm.]
  » Are we working on the wrong problem? => Type III errors =>
  » Cost avoidance (Type I vs. Type II errors regarding requirements for changes in technology). [Does the failure to present technological challenges to industry result in marginal improvements in risk reduction?]
The Traditional Risk Management Process

The traditional risk management process is sequential and involves:

- Collecting risk information
- Performing a detailed risk assessment
- Undertaking risk management measures based on existing solutions
TAKE-HOME LESSONS

● An overly comprehensive and proteracted risk assessment process may unjustifiably postpone the implementation of desirable risk reduction measures.

● A more synchronized risk management process is needed, instead of a sequential process; that is, a dual/parallel approach for (1) clarifying risk information and (2) generating information about safer technological alternatives.

● If the technological alternatives are significantly different – rather than marginally different – \textit{comparative}, rather than full, risk assessments can be used. (Structure-activity relationships can be especially useful here.)

● Informational risk management tools focusing on technological alternatives can be valuable for reducing risk, especially if direct risk management measures are not implemented or enforced.
THREE SCENARIOS

1. The present substance/process is either known to be safe or known to be unsafe in a well-characterized manner: This causes neither a problem with a sequential nor with a more synchronized approach.

2. The present substance/process is known to be unsafe but lacking important details/characterization* In this case, following a sequential process creates cost and time problems. Instead of analyzing the lack of safety in detail, it may be more useful to undertake a comparative technology options analysis, with associated comparative risk assessments.

* large inter-individual variability may present formidable risk assessment challenges
Whether to explore alternative solutions depends on the costs and benefits (risk advantages) -- and associated uncertainties -- of various risk-reduction options, including, but not limited to, changes in inputs, final products, or processes.

On the risk side, if the risks associated with the existing alternatives are uncertain*, a determination must be made of whether to undertake a process to (1) further clarify the risks of the original substance or chemical, (2) clarify the risks of the existing alternatives or (3) instead to search for (or design) clearly-safer alternatives. *large inter-individual variability may present formidable risk assessment challenges

On the cost side, if control or risk reduction is expensive, it may be preferable to search for/to develop alternatives, possibly at cheaper costs than controlling the original hazard. Even if shifting to an alternative technology is more expensive, its adoption could be justified because of the greater certainty of lower risks from clearly-safer substitutes.
3. The hazardous nature of the present substance is uncertain*: In this case it is necessary to specify the kind and extent of the uncertainty. Starting from the properties of a substance, an assessment of the hazardous potential of a substance is fundamental. If a substance contains hazardous potential, a synchronized process of further risk assessment, and comparative risk and cost analyses of substitute technologies, as described under scenario (2) is useful.

* large inter-individual variability may present formidable risk assessment challenges
Informational Tools as Risk Management

- Requirements for firms to disclose risk information* to the public (scientific information)

- Requirements for firms to focus on identifying and generating technological options to reduce existing risks (technological information)

  * large inter-individual variability may present formidable risk assessment challenges
The Toxic Release Inventory (TRI)

- TRI is part of the Emergency Planning and Community Right to Know Act (EPCRA).
- Main purpose: “inform communities and citizens of chemical hazards in their areas“
- Requirements for public disclosure of hazardous releases.
- The releases covered by TRI number 650 substances.
- Firms which annually produce more than 25,000 pounds or use more than 10,000 pounds of the substances (and have more than 10 employees) have to report their releases of these substances.
- Firms need to report their current pollution prevention efforts.
The Massachusetts Toxics Use Reduction Act (TURA)

Two essential extensions beyond TRI

1. TURA also requires data about the use of chemicals (not only releases)

2. TURA requires facilities “to undergo a planning process to identify opportunities for toxics use reduction” beyond what is already being done
TURA: Effects

Between 1990 and 2000, Facilities

- Reduced the use of toxic substances by 45%
- Reduced by-products and waste per unit of product by 69%
- Reduced releases by 92%
- Reduced toxics in products by 60%
- In a survey, firms declared that they saved more money by implementing safer alternatives in the production process, than they spent for complying with TURA
Conclusions

- Informational risk management tools can be valuable, even in the case that other risk management measures are not implemented or enforced.
- However, a traditional sequential risk management process tends to postpone risk reduction measures, and
- a traditional sequential risk management process can consume considerable resources with little clarification of uncertainties, especially if there is large inter-individual variability.
Conclusions (continued)

- The simultaneous promotion of firms‘ public disclosure of risk information, on the one hand, and capacity building by drawing attention to future technological options, on the other hand is a more promising approach.

- In contrast, the European chemicals policy (REACH) continues the tradition of focusing on addressing the lack of knowledge about risk with regard to existing chemicals. The consideration of alternatives comes very late in the approach. The authorization authority is a weak risk management tool.