Regulatory analysis is a tool regulatory agencies use to anticipate and evaluate the likely consequences of rules. It provides a formal way of organizing the evidence on the key effects, good and bad, of the various alternatives that should be considered in developing regulations.

The motivation is to (1) learn if the benefits of an action are likely to justify the costs or (2) discover which of various possible alternatives would be the most cost-effective.

A good regulatory analysis is designed to inform the public and other parts of the Government (as well as the agency conducting the analysis) of the effects of alternative actions. Regulatory analysis sometimes will show that a proposed action is misguided, but it can also demonstrate that well-conceived actions are reasonable and justified.
Benefit-cost analysis is a primary tool used for regulatory analysis.

Where all benefits and costs can be quantified and expressed in monetary units, benefit-cost analysis provides decision makers with a clear indication of the most efficient alternative, that is, the alternative that generates the largest net benefits to society (ignoring distributional effects).

This is useful information for decision makers and the public to receive, even when economic efficiency is not the only or the overriding public policy objective.
Our Goal

An appropriate characterization of science to understand the health benefits of a regulatory action
What is Needed?

- Science
- Assessment approaches
Science: Positive
A process
Hypothesis
Data
Challenge

Policy: Normative
Tradeoffs
Judgment
Legal constraints
Pragmatic

Science Policy: “Trans-science”
How to Use Science in the Face of Uncertainty
• Individual experiments, trials, observations, measurements, *etc.*

• Science may be mandated - *e.g.*, 
  - EU REACH
  - US EPA Pesticides
  - US FDA Pharmaceuticals

• Science may be what is available in reports, scientific literature, *etc.*
Assessment provides understanding of the potential harms from exposure to agents

Safety Assessment
- Identify levels of exposure unlikely to cause harm (e.g., Acceptable Daily Intake, Tolerable Intake, Reference Dose)

Risk Assessment
- Characterize change in probability of outcome with changes in exposure (e.g., Cancer Slope Factors, rate of drug side effects)
Rarely does one scientific study provide the information needed to answer policy questions

- Inadequate scope
- Conflicting studies
- Extrapolations

This means assessments are conducted in a state of scientific uncertainty

Science policy guides the choices and assumptions for dealing with uncertainty
• “Risk assessors might be faced with several scientifically plausible approaches (e.g., choosing the most reliable dose-response model for extrapolation beyond the range of observable effects) with no definitive basis for distinguishing among them. The earlier Committee (NRC 1983 (The Red Book)) pointed out that selection of a particular approach under such circumstances involves what it called a science-policy choice. Science policy choices are distinct from the policy choices associated with ultimate decision-making - NRC 1994 Science and Judgment in Risk Assessment p 27

• “Importantly, remember that risk characterization is not just about science. It makes clear that science doesn’t tell us certain things and that science policy choices must be made.” Page 11
Some Science Policy Choices

- Which study?
  - Epidemiology or toxicology?
  - Toxicology (Which species? Which sex? Which endpoint?)
  - How to reconcile conflicting studies?

- How to estimate exposure? (Measure? Model? Which Model?)

- How to estimate dose-response?

- Report single estimate of risk or range to reflect uncertainty?
### Different Science Policy Choices

<table>
<thead>
<tr>
<th>Chemical</th>
<th>US EPA Maximum Contaminant Level</th>
<th>WHO Drinking Water Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,2 Dichloroethane (solvent, intermediate)</td>
<td>5 µg/L</td>
<td>30 µg/L</td>
</tr>
<tr>
<td>Dichloromethane (solvent)</td>
<td>5 µg/L</td>
<td>20 µg/L</td>
</tr>
<tr>
<td>Cadmium</td>
<td>5 µg/L</td>
<td>3 µg/L</td>
</tr>
</tbody>
</table>
### Different Science Policy Choices

<table>
<thead>
<tr>
<th>Apple Insecticide</th>
<th>US EPA MRL</th>
<th>Codex MRL</th>
<th>EU MRL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorpyrifos</td>
<td>0.01 ppm</td>
<td>1 ppm</td>
<td>0.5 ppm</td>
</tr>
<tr>
<td>Dicofol</td>
<td>10 ppm</td>
<td>-</td>
<td>0.02 ppm</td>
</tr>
<tr>
<td>Permethrin</td>
<td>0.05 ppm</td>
<td>2 ppm</td>
<td>0.05 ppm</td>
</tr>
</tbody>
</table>
Making Science Based Regulation Work

- Processes
- Capacity
Processes for Good Science for Good Regulation

• Explicit Guidelines
  • Identify science policy choices and how they will be addressed
  • Provide guidance on methods and approaches to Agency assessors and others
  • Develop clear guidelines on how scientific information and uncertainty will be communicated to policy makers and stakeholders
Processes for Good Science for Good Regulation

- Transparency
  - Make assessment practices and processes available
  - Make results of specific assessments, including science policy choices, easily available to stakeholders
Processes for Good Science for Good Regulation

- Peer Review
  - Work with outside scientific experts in identifying science, assessing risk and communicating results
  - Use formal peer review processes to enhance quality of assessment
  - Review the analysis, not just the science
Building Capacity to Bring Science to Regulation

- Enhance agency scientific skills
  - Risk related disciplines
  - Science agencies need economic expertise
  - Economic agencies need science understanding
  - Agency research too?
Building Capacity to Bring Science to Regulation

- Support assessment skills
  - Capacity to conduct risk assessments
  - Ability to review risk assessments - WTO context?
  - Support professional growth of agency assessors

- Develop culture of scientific and analytic excellence
Benefits of Good Science for Good Regulation

• Better information for better regulation

• Ability to make sound risk management decisions

• Better understanding (and maybe support) by stakeholders affected by regulation
Thank You