RCR Forum

The Environmental Implications of Biotechnology

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No matter your research, likely to encounter biotechnology….

<table>
<thead>
<tr>
<th>Color</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red</td>
<td>Medical</td>
</tr>
<tr>
<td>Yellow</td>
<td>Food Biotechnology</td>
</tr>
<tr>
<td>Green</td>
<td>Agriculture</td>
</tr>
<tr>
<td>Blue</td>
<td>Aquatic</td>
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<tr>
<td>White</td>
<td>Gene-based industry</td>
</tr>
<tr>
<td>Grey</td>
<td>Fermentation</td>
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<tr>
<td>Brown</td>
<td>Arid</td>
</tr>
<tr>
<td>Gold</td>
<td>Nanotechnology/Bioinformatics</td>
</tr>
<tr>
<td>Purple</td>
<td>Intellectual</td>
</tr>
<tr>
<td>Dark</td>
<td>Bioterrorism/Warfare</td>
</tr>
</tbody>
</table>
Bob manipulated my DNA. Now, I turn dintrochickenwire into harmless CO\textsubscript{2} and water….

Bob got a nice grant and has written some great journal articles bragging about me ….

I wonder why Bob hasn't noticed that I have no natural competition and that I have an affinity for mammalian tissue….

I’ll bet Bob tastes really good!
L’Acide Case Study

1. Read first 2 pages.
2. Skim the attachment… (Select salient material, depending on your area of expertise).
3. Break into groups (by color of your handout).
4. Discuss the facts first.
5. Share opinions on responsible actions.
6. Find way to reach consensus (not necessarily unanimity).
7. “Hire” a spokesperson.
8. Be ready to share details with the whole group (particularly the ones you brought up in the breakout).
“Hold paramount…”

• Engineers must “hold paramount the safety, health and welfare of the public.”

• Characterizes the need for not only protecting public health and the environment, but to be guardians for sustaining these protections.

• But, how do we do this….?
Contaminant Cleanup Feasibility

1. Protect human health and environment
2. Comply with applicable regs
3. Provide long-term effectiveness & permanence
4. Reduce toxicity, mobility or volume (treatment)
5. Provide short-term effectiveness
6. Consider ease of implementation
7. Consider cost
8. Gain State’s acceptance
9. Gain community’s acceptance
Chaos

Chain of events       Actual outcome       Probability of outcome at outset

Subsequent event series_{1...n} -> Desired environmental outcome 0.970

Subsequent event series_{1...p} -> Fortuitous, positive environmental impact 0.003

Subsequent event series_{1...q} -> Neutral environmental impact 0.026

Subsequent outcome series_{1...r} -> Unplanned negative environmental impact 0.001

Initial event

Mitigating measures

Present

Future
Improve desired outcome, but at what cost?

<table>
<thead>
<tr>
<th>Chain of events</th>
<th>Actual outcome</th>
<th>Probability of outcome at outset</th>
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</thead>
<tbody>
<tr>
<td>Initial event</td>
<td></td>
<td>0.975</td>
</tr>
<tr>
<td>Subsequent event series ____n</td>
<td>Desired environmental outcome</td>
<td>0.975</td>
</tr>
<tr>
<td>Subsequent event series ____p</td>
<td>Fortuitous, positive environmental impact</td>
<td>0.002</td>
</tr>
<tr>
<td>Subsequent event series ____q</td>
<td>Neutral environmental impact</td>
<td>0.020</td>
</tr>
<tr>
<td>Subsequent outcome series ____r</td>
<td>Unplanned negative environmental impact</td>
<td>0.003</td>
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</table>

Present  

Future
**Decision Tree (hypothetical)**

Spores and crystalline insecticidal proteins

- **First Order Outcome**
  - Efficacious with no impacts
  - Efficacious with no human health impacts, but with ecological impacts
    - Non-target effects
      - Biodiversity effects
    - Pest resistance
    - Efficacious with agricultural effects
      - Crop damage
  - Efficacious with human health impacts, but without ecological impacts
    - Direct poisoning*
      - Indirect contamination (e.g. track-in)
    - Cross-resistant bacteria
    - Transgenic food problems
  - Nonefficacious

- **Second Order Outcome**

- **Likelihood**
  - 0.810
  - 0.005
  - 0.001
  - 0.010
  - 0.020
  - 0.002
  - 0.030
  - 0.020
  - 0.002
  - 0.100

- **Importance**
  - Environment
  - Public Health
  - Food Production
  - 1
  - 5
  - 3
  - 2
  - 3
  - 4
  - 5

*This has its own decision tree according to vulnerability index, i.e. percentile exposure (high to no exposure) and sensitive subpopulations (children, elderly, asthmatic, etc.).

1 = Best; 5 = Worst
## European classes of risks posed genetically modified microorganisms

<table>
<thead>
<tr>
<th>Hazard Level</th>
<th>Description of Microbial Hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Least</td>
<td>Never identified as causative agents of disease in humans and that offer any threat to the environment.</td>
</tr>
<tr>
<td>Hazardous when contained, low human risk</td>
<td>May cause disease in human and which might, therefore, offer a hazard to laboratory workers. They are unlikely to spread in the environment. Prophylactics are available and treatment is effective.</td>
</tr>
<tr>
<td>Severe when contained, moderate human risk</td>
<td>Severe threat to the health of laboratory workers, but a comparatively small risk to the population at large. Prophylactics are available and treatment is effective.</td>
</tr>
<tr>
<td>High human population risk</td>
<td>Severe illness in humans and serious hazard to laboratory workers and to people at large. In general, effective prophylactics are not available and no effective treatment is known.</td>
</tr>
<tr>
<td>Greatest ecological and human population risk</td>
<td>Most severe threat to the environment, beyond humans. May lead to heavy economic losses. Includes several classes, Epl, Ep2, Ep3 (see Table 1.2 for descriptions) to accommodate plant pathogens.</td>
</tr>
</tbody>
</table>
European classes of microbes causing diseases in plants.

<table>
<thead>
<tr>
<th>Biotechnology Class</th>
<th>Description of Microbes in Class</th>
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<tr>
<td>Ep 1.</td>
<td>May cause diseases in plants but have only local significance. They may be mentioned in a list of pathogens for the individual countries concerned. Very often they are endemic plant pathogens and do not require any special physical containment. However, it may be advisable to employ good microbiological techniques.</td>
</tr>
<tr>
<td>Ep 2.</td>
<td>Known to cause outbreaks of disease in crops as well as in ornamental plants. These pathogens are subject to regulations for species listed by authorities in the country concerned.</td>
</tr>
<tr>
<td>Ep 3.</td>
<td>Mentioned in quarantine lists. Importation and handling are generally forbidden. The regulatory authorities must be consulted by prospective users.</td>
</tr>
</tbody>
</table>
The environment can be seen as series of reactors...

Disaster

Project

Hmmmm......
Perception is crucial

• Which line is longer?

The Müller-Lyer Illusion.
Perception is crucial

• Which line is longer?

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The Müller-Lyer Illusion.
Perception is crucial

• Which line is longer?

The Müller-Lyer Illusion.
But sometimes, perception is pretty accurate....

Problem of valuation of environmental resource

• Always a problem with non-monetized valuation
• E.g. what is the value of a life?
• Dilemma of gross domestic product for eco-resources
• Rethinking value (beyond willingness to pay)
Environmental Ethics

What is valued?

Humans exclusively

All cognitive entities

All sentient entities

All biotic entities

All material entities

All entities and ecological phenomenon (abiotic and biotic, plus other values, richness, abundance, diversity, sustainability)
Environmental Ethics

What is valued? Ethical View

Humans exclusively

↓

All cognitive entities

↓

All sentient entities

↓

All biotic entities

↓

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↓

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Anthropocentric
Environmental Ethics

**What is valued?**

- Humans exclusively
- All cognitive entities
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**Ethical View**

- Anthropocentric
- Biocentric
Environmental Ethics

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- Biocentric
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Metric
- Utility
- Duty
- Empathy
- Sustainability
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- Duty
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Function

- Harm Principle
- Categorical Imperative
- Tragedy of the Commons
- Veil of Ignorance

Valuation

- Willingness to Pay
- Non-monetized Value
Environmental Ethics

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Valuation

- Willingness to Pay
- Non-monetized Value

Framework

- Consequentialism/Teleology
- Deontology
- Rawlsianism
- Deep Ecology
Environmental Legislation

Sea change
• Sources
• Ambient

(From D. Allen & D. Shonnard, Green Engineering, Prentice-Hall, 2002)
Factors increasing perceived risk:
(after Covello, 1992)

1. Possible Severely Negative or Catastrophic Outcome
2. Unfamiliarity with Situation and Potential Risks
3. Inability to Explain Processes and Mechanism
4. Little Certainty in the Science and Engineering
5. Perception of Personal Control
6. Involuntary Exposures to Risks
7. Risk to Children and Sensitive Groups
8. Long-term Exposures, Latency Periods, Chronic Risk
9. Possible Transgenerational Exposures and Risks
10. Uncertainty about Potential Victims
... and the risk is perceived to increase even more when ...

- Greater “dread”
  - Major problem for nuclear power industry
- Mistrust of corporate or governmental partners
  - Guilt by association
- Negative media attention
- A history of accidents and failures at this site or in similar situations
- Benefits are not clear
- Mistakes are irreversible
  - Global climate change, for example
So, then what is risk, really?

- Definition: Probability of harm or loss
- Part of our everyday lives
  - Different for each of us
  - Basis for decision-making
- But is it *quantifiable*?
… depends on how you ask but,…

• Yes it is quantifiable:
  ✓ Risk = f(Hazard x Exposure)

• A probability, a fraction

• Part of our everyday lives
  – Different for each of us
  – Basis for decision-making
Risk Assessment Defined:

Risk assessment is a process where information is analyzed to determine if an environmental hazard might cause harm to exposed persons and ecosystems.

Paraphrased from the “Risk Assessment in the Federal Government” (National Research Council, 1983)
Different Processes at Work: Not everyone thinks like you do….*

<table>
<thead>
<tr>
<th>Analytical Phase</th>
<th>Risk Assessment Processes</th>
<th>Risk Perception Processes</th>
</tr>
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<tbody>
<tr>
<td><strong>Identifying risk</strong></td>
<td>Physical, chemical, and biological monitoring and measuring of the event</td>
<td>Personal awareness</td>
</tr>
<tr>
<td></td>
<td>Deductive reasoning</td>
<td>Intuition</td>
</tr>
<tr>
<td></td>
<td>Statistical inference</td>
<td></td>
</tr>
<tr>
<td><strong>Estimating risk</strong></td>
<td>Magnitude, frequency and duration calculations</td>
<td>Personal experience</td>
</tr>
<tr>
<td></td>
<td>Cost estimation and damage assessment</td>
<td>Intangible losses and non-monetized valuation</td>
</tr>
<tr>
<td></td>
<td>Economic costs</td>
<td></td>
</tr>
<tr>
<td><strong>Evaluating risk</strong></td>
<td>Cost/benefit analysis</td>
<td>Personality factors</td>
</tr>
<tr>
<td></td>
<td>Community policy analysis</td>
<td>Individual action</td>
</tr>
</tbody>
</table>

*Adapted from K. Smith, 1992
Dose-Response: A Way to Define a Hazard

Adverse Effect

Dose

A

B

C

B

NOAEL
Dose-Response: No threshold for cancer

Cancer

Non-cancer

Adverse Effect

Dose

NOAEL
Dose-Response: Safety in Reference Dose

\[
RfD = \frac{NOAEL}{UF_{inter} \times UF_{intra} \times UF_{other}}
\]

Dose vs. Adverse Effect
Dose-Response: Safety in Reference Dose

\[
RfD = \frac{\text{NOAEL}}{\text{UF}_{\text{inter}} \times \text{UF}_{\text{intra}} \times \text{UF}_{\text{other}}}
\]

Where:
- NOAEL: No Observed Adverse Effect Level
- RfD: Reference Dose
- UF: Uncertainty Factor
- inter: inter-species
- intra: intra-species
- other: other factors
Improved Certainty from Better Measurements

\[ \text{RfD} = \frac{\text{NOAEL}}{\text{UF}_{\text{inter}} \times \text{UF}_{\text{intra}} \times \text{UF}_{\text{other}}} \]
Exposure ...
Calculating Exposures:
Amount of Hazard Reaching Us

\[ E = \int_{t_1}^{t_2} C(t) \, dt \]

Where,

\( E \) = personal exposure during time period from \( t_1 \) to \( t_2 \)

\( C(t) \) = concentration at interface, at \( t \).
Exposure bridges the physical and social sciences

\[ E = \int_{t_1}^{t_2} C(t) \, dt \]

Where,

- \( E \) = personal exposure during time period from \( t_1 \) to \( t_2 \)
- \( C(t) \) = concentration at interface, at \( t \).
Discussion Questions

• What principles of research ethics are conflicting in this example?
• Is there more information you need to help you resolve this conflict?
• How should this conflict be resolved?
It’s a matter of trust….

• This is a commodity that can be lost easily but regained with much difficulty….

• Numerous examples of loss of trust in sciences….
An 6-step approach to ethical decision making (from Resnik)

1. State or define the problem/issue
2. Gather information
3. Delineate options.
4. Apply different values, rules, principles, regulations to the different options.
5. Resolve conflicts among values, rules, etc.
6. Make a decision and act
A few final words…

• Do you agree with the risk paradigm?
• Should it be evidence based?
• How about the precautionary principle?
Trust is what it’s about….

• *Ethike aretai*
  – Engineering needs *character*
  – Engineering needs *skill*

• *Credat emptor!*

• Resolve today to keep building competence and character.
If you have questions, contact me….

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- 919-541-3306