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Assessing Risk from Transgenic plants: The next step Forward

Risk & Risk Assessment

Rolf Skjong, DNV
Background- Risk Assessment

- Risk
  - **What?**
  - Stan Kaplan’s Theorems
    - Theorem 1: 50% of the problems in the world result from people using the same words with different meanings
    - Theorem 2: The other 50% come from people using different words with the same meaning
  - No international standard exists, except for specific topics
  - Specialists are aware of many “risk dialects”
- Risk:
- What?
- A Test:
  - What is the risk involved, if you fall out of an airplane without a parachute?
    - A: Big risk – almost certain of dying
    - B: No risk – almost certain of dying
  - An experienced risk analyst may draw the conclusion:
    - A is an engineer
    - B is an economist
- A is right that risk relates to loss
- B is right that risk relates to uncertainty
Risk

- Risk
- **What?**
- Standard definition
- *Risk is a combination of probability and consequence of adverse events*
- Quantitative:

\[ Risk = Probability \times Consequence \]

\[ R = P \times C \]

\[ R = \Sigma P_i \times C_i \]
Individual Risks

Presented as, for instance, the annual probability of death

- 0.1  Killed, as king of Norway, AD 1000
- 0.01 All causes
- 0.001 Lowest risk of mortality when we are 5-15 years old (OECD)
- 0.0001 A mother during labour (OECD)
- 0.00005 Fatal car accident
- 0.00001 Cancer caused from daily consumption of peanut-butter
- 0.00001 Female murdered by husband or lover
- 0.000001 Killed by lightning in Norway
- 0.0000001 Asteroid impact/gamma-jet killing everyone
Consequences:
- Probability of being killed by fireworks is $10^{-8}$ annually
- Probability of all of us being killed by asteroid impacts or gamma bursts from collapsing hypernovas is also $10^{-8}$ annually
- Same individual risk of dying
- Global risk $10^{-8} \times 6 \times 10^9 = 60$ fatalities/annually
- Still global extinction once is different from 60 fatalities annually
- This is normally dealt with in the acceptance criteria
Societal Risk or Group Risk

- Reflects societal risk aversion against large accidents
- 50 fatalities in one accident (bus crash) is less tolerable than 50 fatalities in 50 car accidents
- Presented in FN diagrams (Frequency of N or more fatalities)
- Many countries and industries are used to quantitative acceptance criteria for societal risk
The Perception of Risk—Research issue in Social Sciences

• The same factual, objective, defined risk is differently perceived.
• There are several ways to confirm this:
  – Surveys
  – Observe factual behaviour/decision making
  – Observation of willingness to pay (e.g. for insurance or risk prevention)
• Such studies are published quite frequently
• Significant to communicating risk.
Risk – Perception

Natural Mineral Water

From King Haakon’s Radioactive Alkaline Spring (in Larvik)

FARRIS still not Prohibited
Risk – Social Science

- Social Sciences: Risk has many other as important characteristics other than P&C.
  - Voluntary?
  - Evenly distributed?
  - Just?
  - Ordinary?
  - Catastrophic?
  - Regular?
  - Familiar?
  - Necessary?
  - Etc.
Risk – Technology

- Technological Sciences: For the same risk (PxC) there are **perception biases** relating to:
- Characteristics of the risk
- Personal characteristics
- There are differences in perception relating to:
  - Nationally
  - Gender
  - Race
  - Age
  - Occupation
  - Worldview (Hierarchists, Egalitarians, Fatalist, Individualist)
  - Etc.
<table>
<thead>
<tr>
<th>Conversion Factors: Risk as Is/Risk as Perceived (Litai)</th>
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</thead>
<tbody>
<tr>
<td><strong>Volition</strong></td>
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<td><strong>Severity</strong></td>
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<td><strong>Origin</strong></td>
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<td><strong>Effect Manifestation</strong></td>
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<td><strong>Exposure Pattern</strong></td>
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<td><strong>Controllability</strong></td>
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<td><strong>Familiarity</strong></td>
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<td><strong>Benefit</strong></td>
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<tr>
<td><strong>Necessity</strong></td>
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</table>
Conversion Factors: Risk as Is / Risk as Perceived (Litai et al.)

GM Food Is:

- Voluntary - Involuntary
- Ordinary - Catastrophic
- Natural - Man-made
- Delayed - Immediate
- Regular - Occasional
- Controllable - Uncontrollable
- Old - New
- Clear - Unclear
- Necessary - Luxury

Conversion Factor: $100 \times 20 \times 10 \times 10 = 200,000$

over Voluntary/Natural/Controllable/Old

#### Five-Hundred Life-Saving Interventions and Their Cost-Effectiveness

<table>
<thead>
<tr>
<th>Number of Measures</th>
<th>587</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range</td>
<td>Negative —&gt; 10 billion $/life-year saved</td>
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<tr>
<td>Median</td>
<td>42,000 $/life-year or 1.47 million $/life</td>
</tr>
<tr>
<td>Median Medical Interventions</td>
<td>19,000 $/life-year</td>
</tr>
<tr>
<td>Median Injury Intervention</td>
<td>48,000 $/life-year</td>
</tr>
<tr>
<td>Median Toxin Control</td>
<td>2.8 million $/life-year</td>
</tr>
</tbody>
</table>
Expert Judgement

♦ The use of experts may introduce what we wish to avoid: Subjectivity
♦ Risk assessment wishes to reproduce expert’s evidence, not just expert judgement
♦ Problem: Expert judgement is subject to biases (risk as is/risk as perceived)
♦ Many techniques exist to extract expert judgement
♦ Most popular method: Delphi technique
Expert Judgement by Delphi Technique

♦ Term ‘Delphi’ refers back to Greek history (‘Oracle in Delphi’)

♦ Many variations and adaptations of Delphi technique.

♦ Delphi 5 steps:
  1. Select a group of experts on the topic in question (> 3)
  2. Present problem in detail
  3. Solicit, in isolation, their independent estimates on the value of a particular parameter, and evidence for their choice (Note: Parameter not risk)
  4. Provide initial results, evidence and reservations to all experts. Go back to Step 3 at least once, until experts do not change view when presented with other experts choice and evidence.
  5. Use expert judgement to estimate mean value and standard deviation
Expert Judgement by Delphi Technique

- Normally the process converges
- But, sometimes experts agree to disagree

- For example in the risk assessment of the possible collapse of the West Antarctic Ice Sheet (May increase water levels globally by 5 meters)

DNV in association with British Antarctic Survey carried out the Assessment
Background- Risk Assessment

- Nuclear Industry in 60s: Probabilistic Safety Assessments
- Chemical Industry in 70s: QRA, Seveso Directive I and II
- Offshore Industry in 80s: QRA, Industrial Self Regulation Regime in Norway, Safety Case Regimes in UK
- Shipping Industry in 90s: FSA
- Today/Regulatory: Seen as critical in most sectors for managing risk with emerging technology
- Today/Industry: Technological risk, Economic/Financial Risk, Project risk etc
Two Main Uses

• Risk analysis as a foundation for decision making (e.g. a license to build a nuclear power plant or offshore installation). This is often called a "Safety Case" regime.

• Risk analysis to investigate endeavours to reduce risk to a population (all cars, all ships etc.)

• EU/GMO adhere to the "Safety Case" model.
Risk Analysis

- No international standard for risk analysis exists that can be applied to more than one specific field.
- The EU organised a seminar on "standardization" in May 2000.
- The participants perceived both the process of risk analysis and the techniques employed as generally standardized.
- There are many international standards applicable to specific sectors.
- For nuclear power: IAEA, OECD, NRC, ASME, National standards (i.e. many documents which together define a standard and a regime for regulation).
- "Dangerous" industry: Controlled by both national standards and, for instance, EU directives (SEVESO)
- Ships: IMO (UN organisation) FSA standard
- GMOs: EU directive (requires that a risk analysis is conducted, but no requirements for how it is carried out).
Risk Analysis

• A risk analysis can take many forms:
  – From: Detailed quantitative analyses that involve hundreds of experts, extensive modelling and a vast range of data.
  – To: Qualitative analyses of decision alternatives

• Participating in the process is as essential to the learning process as reading the final conclusion.

• Risk analysis involves rational support of decision making under uncertainty.

• …, but there seems to be two contrasting attitudes:
  – Risk analysis as analysis of uncertainty
  – Risk analysis is impossible due to uncertainty
Risk Analysis

• Most methods and tools developed in the nuclear industry

• Risk analysis "sold" when realized that the "Three Mile Island Scenario" was identified and analysed using risk analysis.

• Due to the large consequences, effort is made to document that there are very small likelihoods by analysing in detail the:
  – Redundancy,
  – Backup,
  – Emergency procedures,
  – Handling of discrepancies
  – Model: Large Fault-trees, small event trees
Risk Assessment Process

Preparatory Step
- Definition of Goals, Systems, Operations
- Hazard Identification
- Scenario definition

Step 1
Hazard Identification

Step 2
Risk Analysis
- Cause and Frequency Analysis
- Consequence Analysis
- Risk Summation

Step 3
Risk Control Options
- Options to decrease Frequencies
- Risk Controlled? (Yes, No)
- Options to mitigate Consequences

Step 4
Cost Benefit Assessment

Step 5
Recommendations for Decision Making
- Reporting
## Risk assessment

<table>
<thead>
<tr>
<th>Step</th>
<th>Question</th>
<th>Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>What might go wrong?</td>
<td>Hazard identification</td>
</tr>
<tr>
<td>2</td>
<td>How often, how likely? How bad?</td>
<td>Risk analysis&lt;br&gt;Frequencies, probabilities&lt;br&gt;Consequences&lt;br&gt;Risk = probability x consequence</td>
</tr>
<tr>
<td>3</td>
<td>How can matters be improved?</td>
<td>Risk control options identification</td>
</tr>
<tr>
<td>4</td>
<td>How much? How much better?</td>
<td>Cost benefit evaluation</td>
</tr>
<tr>
<td>5</td>
<td>What actions are worthwhile to take?</td>
<td>Recommendation</td>
</tr>
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</table>
Drawbacks of Risk Analysis

• Hazards that are not identified will not be analysed
• Assumptions and uncertainty in collected data and models will be integrated and echoed in the final results.
• Assumptions are documented, and the consequences of assumptions are presented
• Uncertainties concerning assumptions can be structured and quantified.
Spread of BSE and Creutzfeldt-Jacob’s Disease

- DNV has conducted several risk analyses in response to the outbreak of BSE in Britain
- These analyses are available on the internet:
Spread of BSE and Creutzfeldt-Jacob’s Disease

- Each analysis conducted follows standard procedures for risk analysis.
- Involved “stakeholders” as far as the authorities requested
- Multidisciplinary teams to do the job
- Use of event-trees, data, and expert opinions
- Every assumption, presumption, and decision is documented – complete insight.
- Uncertainties are evaluated and modelled – not hidden
- Uncertainties in the results are presented to the decision-makers.
- Present both personal risk and societal risk
Spread of BSE through destruction of bovine (the Foot and Mouth Epidemic)

• Foot and Mouth disease required the destruction of more bovine than capacity would allow.
• The alternatives:
  – Incinerate outdoor
  – Bury
• But some of the destroyed bovine were infected with BSE: What about the risk of spreading?
• Standard risk analysis was carried out shortly afterwards.
• The construction of event-trees showing all possible routes through which infection may spread (considering both alternatives).
• A lot of necessary data was available from DNV’s previous work with BSE.
Spread of BSE through destruction of bovine (the Foot and Mouth Epidemic)

• For instance, incinerating bovine cadavers can trigger the spread of BSE:
  – by inhaling smoke-particles
  – by eating food from crops grown in the area.
  – through groundwater
  – through water reservoirs (lakes, rivers etc.)
Spread of BSE through destruction of bovine (the Foot and Mouth Epidemic)

- **Destroyed in fire**
  - Infectivity burned: $5.0 \times 10^{-2}$ human oral ID50
  - Remaining in ash: 0.90
- **Leached out**
  - Ground water: 0.0500
  - Infiltration: 0.9500
- **Buried in pits**
  - Remaining: 0.990
- **Decays in ground**
  - 0.9500
- **Spilled before burial**
  - Run-off: 0.010
  - Infiltration: 0.990
- **Inhaled**
  - Inhalation: 5.8E-05
  - Run-off: 0.70
  - Infiltration: 0.30
  - Consumed on crops: 1.2E-08
  - Washed off: 0.999999
  - Infiltration: 0.990
- **Fall on populated areas**
  - Particles in smoke: 0.10
  - 0.160
  - Run-off: 0.010
  - Infiltration: 0.900
- **Fall on unprocessed crops**
  - 0.015
  - 0.100
  - Run-off: 0.010
  - Infiltration: 0.900
- **Fall on surface water**
  - 0.006
  - Run-off: 0.010
  - Infiltration: 0.990
- **Fall on other land**
  - 0.819
  - Run-off: 0.010
  - Infiltration: 0.990
Result

- The destruction of 100 milking cows, all beyond the age of 5, was used as a reference.
- Incineration: 0.00009 [0.0000005-0.02] ID$_{50}$ doses
- Burial: Risk is higher than incineration by a factor of 10
- Individual risk is deduced using a linear dose-response model
Conclusion

- Risk Analysis is a well established and widely accepted procedure within all "dangerous" industries.
- Many different types of risk analyses are applied within the environmental sector.
- Parallels with transgenic plants
  - Large consequence
  - Large uncertainty
  - Lack of data
  - Decision making in under uncertainty