Quantitative Risk analysis (QRA) and risk management: can it be used to inform spectrum policy decisions?

Dr. Francisco J Zagmutt
Managing Partner
EpiX Analytics

www.epixanalytics.com
Agenda

- Introduction by Robert Pavlak - growing need for quantitative/statistical analysis to:
  - Inform trade-offs between stakeholder interests
  - Make more productive use of spectrum authorizations

- Introduction to QRA for decision support
  - What are risks and opportunities
  - How QRA works
  - QRA vs worst-case scenarios

- Experiences in other industries/agencies
  - Why do they do QRA? Regulatory background
  - What can be learned from them

- Discussion
  - How can QRA be used in spectrum policy by the FCC?
  - How do we get there? Short and long-term goals, attainable steps
Who is this guy and his company?

1. Managing partner at EpiX Analytics - specialized risk analytics and decision-modeling company

2. Focus: Quantitative risk analysis & modeling to improve decision-making

3. Experience in a wide range of industries:
   - Pharmaceuticals
   - Mining
   - Manufacturing
   - Transportation
   - Insurance
   - Outcomes research / pharmacoeconomics
   - Financial industry
   - Health / Food safety
   - Energy, oil & gas
   - Many others....
Some of the institutions we have helped
What is risk analysis?

- Risk is usually defined as a triplet:
  1. What can go wrong (event)?
  2. How likely is it (probability)?
  3. How big is the impact?

- Provides informative assessment of probability -> more informative than simply “possible” events/impacts

- Opportunities (risks that we would like to happen) or benefits can also be quantified

- Quantitatively balancing risk and benefits requires a common “currency”
Key to consider

- Provides method to make **decisions** under **uncertainty** - is a **decision** tool

- Uses what is **currently known** about the risk issue

- It makes no scientific judgment, i.e. keeps neutral

- It has to respond to decision questions - often has to make approximations and assumptions

- Has to **deal with data available**
  - Not a wish list
  - So analyses need to be constructed around available data
  - The impact of uncertainty in the decision must be assessed

- Quantification requires a model – typically Monte Carlo simulation
A motivational example

- We would like to estimate the time to complete a new R&D project
- Several steps, some of them are conditional (sequential) and some are parallel
- There is a 20% chance that the first pilot fails, creating delays
- Experts provide estimates below for completion of each step
- Decision question: **how long will it take to finish the project?**

<table>
<thead>
<tr>
<th>Task</th>
<th>Duration (weeks)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Min</td>
<td>ML</td>
<td>Max</td>
</tr>
<tr>
<td>Design prototype</td>
<td>3</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>Seek internal approval</td>
<td>3</td>
<td>6</td>
<td>21</td>
</tr>
<tr>
<td>Get supplies</td>
<td>2</td>
<td>4</td>
<td>12</td>
</tr>
<tr>
<td>Build pilot</td>
<td>10</td>
<td>13</td>
<td>16</td>
</tr>
<tr>
<td>Test</td>
<td>2.5</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Rebuild?</td>
<td>10</td>
<td>13</td>
<td>16</td>
</tr>
<tr>
<td>Test again?</td>
<td>2.5</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Write report</td>
<td>4</td>
<td>5</td>
<td>8</td>
</tr>
</tbody>
</table>

Using **stats** we can say

- Min: 27 weeks
- ML: 38.2
- Mean: 42
- Max: 73.4

**Probabilities of making it on time?**

**a.k.a. Worst-case scenario**
Using QRA we can also calculate probabilities and confidence

- Min, ML, mean, and max same as for stats
- We are 95% sure that it will take from 32 to 60 weeks

- How do our results compare to the max, worst-case scenario of 73?
  - “Feasible” max: e.g. 99%=62.4 “Only 1 out of 100 projects would last more than 62.4 weeks”
  - 99.9=66.5 - Only 1 out of 1,000 would last more than 66.5 weeks. Still far from 73 weeks!

ProjectQRA.xlsx
What variable affects our results the most?

![Bar chart showing project inputs ranked by effect on output, with Initial pilot failure at 55.296, Seek internal approval at 48.029, Get supplies at 45.722, Build pilot at 44.362, Write report at 43.726, Test at 43.669, and Design prototype at 43.264. The baseline is 42.195.]

© EpiX Analytics LLC
Methods to predict effect of future options/interventions

**Single-point estimates:**
One set of inputs, one output

**Sensitivity analysis:**
Change in outcome by varying one (or more) variable(s) at a time

**Scenario analysis:**
Base-case, best-case, **worst-case**. No sense of likelihood

**Statistics:**
Probabilistic, can only *predict* based on observed (past) events. Can’t predict structural changes.

**RA and simulation modeling:**
Prediction of future changes, with probabilities. Quantification of risk drivers
Why do a risk analysis anyways? (in government)

Because they said so....

https://sasoc.files.wordpress.com/2010/10/billclinton3.jpg


https://http://www.history.com/images/media/slideshow/george-w-bush/george-w-bush-41bush.jpg
Executive order 12866 – 1993 (Clinton)
• “Significant regulatory actions” be submitted for review to the Office of Information and Regulatory Affairs (OIRA).
• What is “significant”?
  • Annual effect on Economy of \( > 100 \text{M} \), or
  • Adversely affect economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities
• Thus, risk analysis and cost/benefit analysis needed
  https://www.whitehouse.gov/omb/inforeg_riaguide/

Circular A-4 2003 (Bush)
• Requires use of both benefit-cost analysis (BCA) and cost-effectiveness analysis (CEA) to evaluate regulatory choices. CEA preferred when benefit not quantifiable
• https://www.whitehouse.gov/sites/default/files/omb/assets/OMB/circulars/a004/a-4_FAQ.pdf

Executive Order 13563 – 2011 (Obama)
• Encourages agencies to consider regulatory approaches that reduce the burden of regulation while maintaining flexibility and freedom of choice for the public
• Requires agencies to quantify anticipated benefits and costs of proposed rulemakings as accurately as possible using the “best available techniques”
The Reg Map

Informal Rulemaking

Step One
Initiating Events

Step Two
Determination Whether a Rule Is Needed

Step Three
Preparation of Proposed Rule

Step Four
OMB Review of Proposed Rule

Step Five
Publication of Proposed Rule

Step Six
Public Comments

Step Seven
Preparation of Final Rule, Interim Final Rule, or Direct Final Rule

Step Eight
OMB Review of Final Rule, Interim Final Rule, or Direct Final Rule

Step Nine
Publication of Final Rule

Specific Analyses for Steps Three and Seven

Regulatory Planning and Review (E.O. 12866)
Would the rule have a $100 million annual impact, raise novel issues, and/or have other significant impacts?
→ If yes
   Prepare economic impact analysis.

Regulatory Flexibility Act (5 U.S.C. 601-612)
Is a notice of proposed rulemaking required by law?
→ If yes
Would the rule "have a significant economic impact on a substantial number of small entities"?
→ and yes
   Prepare regulatory flexibility analysis.

Note: Under limited circumstances analyses also are required for certain interpretive rules involving internal revenue laws (5 U.S.C. 603, 604).
All great but... Executive Order 12866 and circular A-4 **don’t apply to independent agencies**

e.g. Congressional Research Service, review of analysis requirements in rulemaking (2014) [https://www.fas.org/sgp/crs/misc/R41974.pdf](https://www.fas.org/sgp/crs/misc/R41974.pdf)

The most extensive and broadly applicable of the requirements are in Executive Order 12866 and OMB Circular A-4, but they **do not apply to independent regulatory agencies**. The statutes that provide rulemaking authority to independent regulatory agencies often require them to “consider” regulatory costs and benefits, and they **often have less explicit requirements for cost-benefit analysis, if any**. An OMB report indicated that independent regulatory agencies provided some information and costs and benefits in 76 of the 118 major rules they issued from FY2003 to FY2012. Cabinet departments and other agencies estimated monetary costs and benefits for some, but not all, of their rules.

Several bills have been introduced in the 113th Congress that would codify and/or expand the current requirements for cost-benefit analysis. Congress could decide to keep the existing analytical framework in place, or could enact one or more of these reform proposals. Another more comprehensive approach could be to consolidate all of the analytical requirements in one place, and perhaps expand those requirements to include more agencies or rules, or to require different types of analysis. To do so, or to simply cover independent regulatory agencies by the executive order, the President could arguably amend Executive Order 12866 and OMB Circular A-4, or Congress could enact legislation. Any such changes must be cognizant of the state of existing law and practice in this area, and the resources and data required for agencies to carry out the analyses.
“While many of the principles presented in this Memorandum may be relevant to other fields, such as financial or information technology risk analyses, the focus of this Memorandum is on those risk analyses related to environmental, health, and safety risks” Page 2 of M-07-24


In summary, risk analysis in government is usually “health-oriented” because:

- Independent agencies not required to do it (EPA is the exception)
- Term “risk assessment” or “risk analysis” historically associated with “harm”, but methods are similar for “regulatory impact analysis” or “Impact assessment”
  - E.g BCA/CEA analysis require a measure of the “harm” or “benefits”, so risk analysis is often done without being called QRA.
What are others doing in the US?

It started with EPA (so under the “health” umbrella):

- History of QRA at EPA (since 80s): [http://www.epa.gov/risk_assessment/history.htm](http://www.epa.gov/risk_assessment/history.htm)
  - Applications: assess health hazards from environment and water.

- Several other agencies actively use it: e.g.
  - USDA – establish policies based on predicted benefits, allocate inspection resources, assess import risks, assess effectiveness of policy changes, quantify performance in achieving standards, identify data gaps
  - FDA – food safety, risk/benefits assessments of interventions/pharma, net clinical-benefits of drugs, etc.
  - Even the fed reserve! Financial risk models (e.g. VaR), and “stress testing” (Dodd-Frank act)
And in Europe – many cases, but the European Food Safety Authority (EFSA) is a good case study

- **Independent** European agency funded in 2002 to provide food risk assessments to EU – separate from EU commission, EU parliament, and EU member states

- Funded with large emphasis on **separation** of risk assessment and risk management

- However, such drastic separation may not provide most informative answer to decision makers

- Emphasis **evolving** to **independence with interdependence** with decision makers/risk management
What can we learn from others?

- "One size fits all" models typically don’t work – but perhaps this approach might be feasible in interference assessment?

- Well defined risk management questions are key to the success of a QRA

- Independence of risk assessors is important, but iterative dialog with risk managers and stakeholders is necessary for success/relevance of modeling

- Methods are still not very standardized – QRA requires skill AND practice
The way forward

- Key to a good start
  - Awareness of QRA methods and limitations - training
  - Start with a small, self contained project that can show the value of the approach, then consider a bigger scope

- Learn from other’s experiences, but perhaps not too much
  - Historical evolution from older agencies not necessarily good to replicate (e.g. EPA vs FSIS)
  - Consider early on how to establish standards and consistency among involved parties
Thanks for your time!

Please feel free to contact me if you have any questions

Francisco J Zagmutt, DVM, MPVM, PhD
Managing Partner
EpiX Analytics

fzagmutt@epixanalytics.com

http://www.bertibenis.it