Putting the Science in Regulatory Science to Address Uncertainties (Newsletter)*

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Environmental regulations are supposed to be based on sound science, yet too often either that science is not presented or is deemed insufficient by permit applicants and others. The result can be administrative appeals and legal challenges that increase time and costs for the applicant and indecision by regulatory agency staff.

At their core, all environmental regulations ask three questions to assess compliance with the relevant law or statute:

1. Will the permitted activity adversely effect the natural environment (forecasting)?

2. Does the operating activity degrade the natural environment (cause and effect)?

3. Are there synergistic or cumulative impacts from multiple activities (spatio-temporal multivariable interactions)?

Answering these questions requires appropriate baseline data. Regardless of permit type or project/activity stage it is necessary to collect physical, chemical, and biological data consistently at defined locations. These data are identified when the sampling program is designed based on the response variable (or variables) of interest and the potential explanatory variables that influence the values observed and measured. These variables are often called dependent (response) and independent (explanatory).

Determining the relevant response and explanatory variables is necessary to demonstrate compliance with CERCLA, CWA, ESA, NEPA, RCRA and all other environmental laws.

The regulatory science that informs technically sound and legally defensible environmental policy and regulatory decisions has two components: analysis of data using appropriate (and correctly applied) statistical models and interpreting the results using established ecological knowledge of ecosystem dynamics.

Environmental data are different from the those commonly used in basic statistics courses in science and business programs. Many familiar statistical models work with financial, economic, and medical data but produce wrong answers with environmental data. As examples, geochemical data (water, sediments, soils, and rocks) cannot have concentrations less than zero and frequently have infrequent very high values which makes descriptions and comparisons based on the normal distribution invalid. Biological data are not continuous like temperature and chemical concentrations; they are counts (integers) or presence/absence (binomial). Biotic data are correctly described and compared using Poisson and logistic distributions, respectively.

Environmental data also have spatial and temporal components that are important in explaining inherent natural variability, making predictions, and determining cause and effect. Many of these values are categories (names) such as locations and seasons. Not all statistical models can incorporates these non-numeric variables.

Another important factor of regulatory science that is rarely addressed is transparency of the analytical tools. Proprietary (closed source) software may use the wrong statistical model (such as calculating a population mean rather than a sample mean). Using open source software allows everyone to examine the equations and assumptions used to generate output which makes the entire process transparent and discourages confirmation bias (testing data to support a priori conclusions).

In a 2007 report by the National Research Council's Committee on Models in the Regulatory Decision Process the authors list seven questions of interest to decision makers and stakeholders:

1. How well do we know model results? What is the precision of the estimates? Can any bias in the estimates be quantified?
2. How large or important are differences between two alternatives?
3. How great are apparent trends over time?
4. How effective are proposed control or management strategies?
5. What is the key source of uncertainty in these numbers?
6. How can uncertainty be reduced?
7. How might results change if one used a different model?

All seven questions are answered when the appropriate statistical models are used.

Companies invest a lot of money collecting baseline and compliance monitoring data. With proper planning collection efforts and analyses supporting regulatory science can more than repay their cost by decreasing decision delays and quantifying the relationships of the permitted operation to the natural environment. With global warming/climate change and societal focus on sustainability understanding a permitted operation's relationship to the natural environment is critical information for permit holders and regulators.

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Rich Shepard
Applied Ecosystem Services, Inc.
503-667-4517
www [dot] appl-ecosys [dot] com